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Overview and brief description
of common abbreviations in the

GxP environment

ABC OF FREQUENTLY USED TERMS AND ABBREVIATIONS IN THE GXP ENVIRONMENT

GxP

GMP
GOOD MANUFACTURUNG PRACTICE

GLP
GOOD LABORATORY PRACTICE

GCP
GOOD CLINICAL PRACTICE

GDP
GOOD DOCUMENTATION PRACTICE

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Foreword

In the dynamic and regulated world of cGxP guidelines (Good Practice), compliance plays a crucial role in ensuring product quality and safety. Particularly in the fields of pharmaceuticals, biotechnology, and medical devices, it is vital to adhere to standards and regulations to ensure successful operations and regulatory compliance.

However, with increasing complexity and global requirements, numerous abbreviations and terms have evolved that can often cause confusion. This compilation does not claim to be exhaustive but is intended to serve as a practical reference to shed some light on the jungle of abbreviations. Since many terms originate from the Anglo-American region, the alphabetical listing prefers to use English terms as the sorting criterion.

Our goal is to provide you with an overview of the most common cGxP abbreviations to help you navigate the technical language better and facilitate communication in your professional life. Naturally, the short explanations provided can only serve as brief references. For more detailed explanations, ample accessible professional literature is available. Whether you are a newcomer to this field or an experienced expert, we hope this little guide of abbreviations is helpful to anyone seeking transparency and clarity in a sometimes overwhelming technical language.

Terms and Definitions

21 CFR – Code of Federal Regulations

The Code of Federal Regulations (CFR) is a systematic collection of the general and permanent rules published in the Federal Register by the departments and agencies of the U.S. federal government. Title 21 of the CFR is specifically dedicated to the regulations of the Food and Drug Administration (FDA) and addresses aspects related to the regulation of food and drugs.

21 CFR Part 11

21 CFR Part 11 is a regulation by the U.S. Food and Drug Administration (FDA) that outlines the criteria for accepting electronic records and electronic signatures. It specifies requirements for the integrity, security, and availability of these records to ensure they are as trustworthy and reliable as traditional paper-based documents.

A

API – Active Pharmaceutical Ingredient

An Active Pharmaceutical Ingredient (API) is the principal pharmacological active substance in a medication that achieves the intended therapeutic effect. APIs are highly pure chemical compounds that are incorporated into strict manufacturing processes to ensure their quality, safety, and efficacy. They are often combined with excipients in medications to enhance the dosage form and stability of the final product.

ALCOA (++) Principle

The ALCOA principle aims to ensure data integrity and data quality in records. ALCOA stands for:

- Attributable – Data must be traceable to a specific source or person.
- Legible – Data must be readable and permanent.
- Contemporaneous – Data should be recorded at the time of the activity or observation.
- Original – Data should be in their original, unaltered form.
- Accurate – Data must be correct and error-free.

The ALCOA++ principle extends the original ALCOA concept to consider additional attributes of data integrity in regulated environments such as the GxP environment. This extension includes further criteria:

- Complete – All data must be complete and comprehensive.
- Consistent – Data should be in a reliable and logical format.
- Enduring – Data must be preserved over time.
- Available – Data should be accessible whenever needed.

Annex 1

Since August 2023, the new Annex 1 is effective in a revised version, with a transition period until 2024. While the basic structure remains the same, the addition of extra subchapters has made the Annex more comprehensive and detailed. The focus is particularly on the production of sterile products to minimize the risk of microbiological, particulate, and pyrogenic contamination. Additionally, the new Annex 1 serves as a guide for the best possible protection of sterile products.

APR – Annual Product Review

The Annual Product Review (APR) required by the FDA is a mandatory process to ensure the quality of pharmaceutical products manufactured or imported in the USA. The APR involves a retrospective, systematic review of all batches, production processes, deviations, complaints, as well as any changes in manufacturing procedures and control methods within a year.

A_0-Value

The standard EN DIN ISO 15883-1 defines the A_0 value as a measure of microbial inactivation during disinfection with moist heat. This value is used to determine the required amount of moist heat in automated washer-disinfectors. The A_0 value represents the time needed to achieve a specific log reduction of microorganisms based on the temperature of the disinfection cycle.

Exposure Time sec.		Temp. °C	A_0-Value
10	600	70	60
1	60	80	
-	6	90	
100	6.000	70	600
10	600	80	
1	60	90	
500	30.000	70	3.000
50	3.000	80	
5	300	90	

Audit

In a GxP environment, an audit refers to a systematic and independent on-site examination conducted to ensure that all processes, systems, and procedures comply with applicable regulations and quality standards. Audits aim to guarantee the integrity and quality of products by identifying weaknesses and risks and assessing the effectiveness of quality control measures. Audits can be performed by various entities, both internally and externally, such as by customers. Distinct in terminology, yet with the same underlying purpose, is an inspection, which may only be conducted by the relevant regulatory authorities.

Audit Trail

The term „Audit Trail“ refers to an organized record of all changes and actions

within a system or document. This logging ensures data integrity and traceability, which are critical for meeting regulatory standards. The audit trail helps to make it clear who made changes, when, and why, making it a vital tool for quality assurance. With the rise of digitalization, the concept has gained significance in relation to data security and integrity, and it is explicitly mentioned in regulations such as 21 CFR Part 11, ALCOA++, or EU GMP Annex 11.

B

Bioburden

Describe the total number of viable microorganisms present on a non-sterilized surface or in the product.

BP – British Pharmacopoeia

The British Pharmacopoeia (BP) is the official compendium of medicinal standards in the United Kingdom, providing comprehensive standards to ensure the quality and safety of medicines. It serves as an important reference for manufacturers, testing laboratories, and regulatory authorities.

C

Calibration

Calibration is the documented comparison of a measurement device to be calibrated with a traceable reference.
All sensors and measurement devices must be calibrated prior to use in a validation study. Calibration results must be documented. Achievable measurement uncertainties must align with application-specific requirements.

- According to ISO/IEC GUIDE 99:2007, calibration is a process that establishes a relationship between measurement quantities and corresponding indications.
- Calibration = determined difference between the measured value and the true value (traceable reference/standard).
- Adjustment = correction of the measured value towards the true value to minimize measurement error and increase accuracy.
- Calibration & adjustment occur throughout the lifetime of a system, instrument, sensor, and must be performed.

- It is part of qualification and validation but does not replace them.
- It includes all sensors and measurement quantities, instruments, or a system, and defines the overall accuracy of the entire measurement chain.
- It refers to the performance and characteristics of sensors, measurement systems, and software.
- It includes general methods of metrology:
    - Definition of the measurement method (environmental conditions; required standards method)
    - Creation of a mathematical model for calibration assessment, including its measurement uncertainty
    - Performance of the calibration
    - Creation of a calibration certificate with details (determined deviation, adjustment, and measurement uncertainty)
- Depending on the process/sensor/measurement quantity, a post-calibration without adjustment is required for verification and documentation purposes after use.

Calibration Protocol

A calibration protocol is a technical document that describes a comprehensive plan or standard operating procedure for conducting the calibration of a device, instrument, or system. It includes all necessary steps and conditions to ensure that the device provides accurate measurements and operates within specified tolerances. A calibration protocol establishes specific calibration requirements, including the methods to be used, calibration intervals, acceptable limits, and the necessary documentation of results.

CAPA – Corrective and Preventive Action

It‘s a systematic approach to identifying and addressing root causes of deviations and implementing preventive measures to prevent their recurrence. A robust CAPA (Corrective and Preventive Action) system includes root cause analysis, the implementation of corrective actions, the evaluation of the effectiveness of these actions, and, of course, comprehensive accompanying documentation.

CC – Change Control

Change control is a systematic and formal process that ensures all changes to products, processes, or systems are carefully planned, assessed, and documented. The primary goal of change control in the GMP (Good Manufacturing Practice) environment is to maintain the integrity and quality of products despite changes and to ensure that these changes meet regulatory requirements.

CFR – Code Federal Regulations

Collection of the general and permanent rules issued by the federal agencies of the USA. In the pharmaceutical and biotechnology industries, 21 CFR plays a particularly central role, as it contains the regulations of the U.S. Food and Drug Administration (FDA) to ensure the safety, efficacy, and quality of pharmaceutical products and medical devices.

CFU – Colony Forming Unit

CFU (Colony Forming Unit) is a unit of measurement used in microbiology to estimate the number of viable microorganisms in a sample. CFUs are crucial for assessing the microbiological contamination of products and materials. A colony-forming unit is defined as a viable microorganism, such as bacteria or fungi, which can multiply and form several colonies during cultivation.

ChP – Chinese Pharmacopoeia

The Chinese Pharmacopoeia (ChP), also known as PPRC, is the official compendium of the People‘s Republic of China and includes comprehensive standards for the purity, description, tests, dosage, safety measures, storage, and potency of medicines. It plays a crucial role in ensuring drug quality in China, similar to the European Pharmacopoeia in Europe and the USP in the USA.

CIP – Clean in Place

This is a procedure for cleaning production equipment and systems without disassembly. CIP (Cleaning in Place) is used in the pharmaceutical industry for cleaning pipes, containers, filling systems, or tanks, for example. The method involves a combination of rinsing, cleaning, and disinfecting with various cleaning agents. Often, sterilization is subsequently carried out using what is known as SIP (Steam in Place).

Cold Chain

A cold chain is a temperature-controlled supply process in which temperature-sensitive products such as food, pharmaceuticals, chemical substances, and biological materials are transported and stored within a specified temperature range throughout their supply chain. The aim is to ensure the quality, safety, and efficacy of these products by strictly adhering to the specified temperature requirements. The cold chain encompasses the entire process, from production through storage, transportation, and distribution to the end consumer.
In the pharmaceutical field, this includes medicines, active pharmaceutical

ingredients (APIs), vaccines, and biological substances. These products are highly sensitive to temperature fluctuations, and any deviation from the recommended range can render them ineffective or even harmful.

Cold Chain Management

Cold Chain Management refers to the comprehensive control and monitoring of all phases within a temperature-controlled supply chain to ensure the integrity of temperature-sensitive products such as food, pharmaceuticals, and biological materials. This encompasses the entire process from production through storage and transportation to final delivery to the end consumer. Efficient Cold Chain Management ensures that these products remain effective and safe and that all relevant regulatory requirements are met.

Compliance

In regulated environments, compliance refers to the adherence to all relevant legal, ethical, and regulatory requirements and standards. In industries such as pharmaceuticals, food, and medical technology, this means ensuring that all processes, systems, and products meet the established regulations and best practices to guarantee safety, efficacy, and quality. Ultimately, it is about ensuring patient safety.

Concurrent Validation

The accompanying validation, also known as concurrent validation, takes place alongside the ongoing routine production. Its purpose is to assess the performance and consistency of the manufacturing process and ensure that quality and regulatory requirements are consistently met.

CPV – Continued Process Validation

Continuous Process Validation (CPV) ensures that production processes and components consistently remain within established quality limits and is considered the third phase of process validation. CPV aims to keep processes continuously under control and maintain quality standards through regular monitoring. Efficient CPV identifies process inconsistencies and enables quick corrective actions.

CQA – Critical Quality Attributes

Critical Quality Attributes (CQAs) are specific physical, chemical, biological, or microbiological properties or characteristics of a product that must be within specified limits, ranges, or distributions to ensure that the desired product quality

is achieved. These attributes are essential for manufacturing and ensuring a consistent level of product quality.

CSV – Computer-System / -Software-Validation

The description refers to Computer System Validation (CSV), which is a critical process to ensure that a computer system or software performs as intended and operates error-free, especially in environments subject to current Good Manufacturing Practice (cGMP) guidelines. The CSV process includes requirements such as risk analysis, planning, testing and validation, documentation, and continuous monitoring. Proper validation of computerized systems is essential in maintaining quality assurance and compliance.

D

Data Integrity

Data integrity refers to the completeness, correctness, consistency, and accuracy of data throughout its entire lifecycle. It is critical for the reliability of data used in regulated industries like pharmaceuticals and medical technology. Data integrity ensures that data is trustworthy and traceable, which is essential for regulatory compliance and for the safety and efficacy of products. It is a key component of the quality assurance system and is mandated by many guidelines and standards as the foundation for compliant quality assurance.

Design Specifications

Design specifications refer to detailed technical documents that describe the requirements and features of a system or product. They define how a system or component should function to meet certain standards and regulatory requirements. These specifications serve as the foundation for the development and validation of systems, ensuring that all relevant aspects such as functionality, safety, and compliance are considered.

Deviation

In the pharmaceutical technical environment, the term „Deviation“ refers to a departure from established standards, procedures, or specifications within a regulated process, such as manufacturing, testing, or quality control of pharmaceuticals. Deviations can be attributed to process errors, human error, or unforeseen events and must be thoroughly and meticulously documented,

investigated, and appropriately rectified to ensure the safety and efficacy of the products.

Deviation Management

Deviation management refers to the structured process for identifying, documenting, investigating, and correcting deviations that occur during the manufacturing, testing, or quality control of pharmaceuticals. This process is crucial to ensure the integrity and quality of products and compliance with regulatory requirements.

Deviation management includes the following steps:

1. Detection: Identification of a deviation from the standard procedure or specification.
2. Documentation: Written record of the deviation, including its details and potential impacts.
3. Investigation: Analysis of the causes of the deviation to determine the origin and reasons.
4. Corrective Actions: Implementation of actions to address the immediate impacts of the deviation.
5. Preventive Measures: Introduction of measures to prevent the recurrence of the deviation.
6. Review and Closure: Evaluation of the effectiveness of the actions taken and formal closure of the deviation.

Effective deviation management is crucial for maintaining regulatory compliance and continuously improving product quality.

DMS – Document Management System

A Document Management System (DMS) is a software solution that organizes, stores, and manages electronic documents within a company. It allows users to efficiently create, edit, store, and retrieve documents while simultaneously monitoring access rights and editing logs. In a large organization, DMS helps optimize the flow of information, meet compliance requirements, and enhance collaboration across different business areas. It can manage both structured data, such as reports and policies, and unstructured content, like emails and multimedia, on a central, accessible platform.

DQ – Design Qualification

Design Qualification (DQ) is the documented verification that the created design documents comply with the user requirements specified in the requirements specification. It also confirms that all necessary design documents for implementation have been prepared, taking into account GMP requirements (laws, guidelines, and the state of the art).

D-Value

The D-value, or decimal reduction time, is the time in minutes required to reduce the microbial population by 90%, corresponding to a one-log reduction. In steam sterilization, the D-value measures the killing efficiency of the process. It is crucial for the development and validation of sterilization procedures, as it ensures that the microbial load is reduced without compromising product integrity.

E

EMA – European Medicines Agency

The EMA, or European Medicines Agency, is an agency of the European Union responsible for the scientific evaluation, supervision, and safety monitoring of medicines in the EU. It plays a central role in the approval of new drugs to ensure they meet high standards of quality, safety, and efficacy. By evaluating and monitoring medicines within the European Union (EU) and the European Economic Area (EEA), the EMA protects and promotes the health of people and animals.

EP – or Ph.Eur European Pharmacopeia

The European Pharmacopoeia (Ph. Eur.) is the primary source of official quality standards for medicines and their ingredients in Europe. The European Directorate for Quality of Medicines & HealthCare (EDQM), a directorate of the Council of Europe, provides scientific and administrative support for it. The governing body of the European Pharmacopoeia is the European Pharmacopoeia Commission, which develops and sets the standards.

EU-GMP – Annex

In the context of the EU GMP (Good Manufacturing Practice) guidelines, the annexes provide supplementary documents that offer specific regulations and guidelines for particular areas of GMP. While the main part of the GMP guidelines covers general requirements for production processes and quality control in

pharmaceutical manufacturing, the annexes delve into particular topics or specialized forms of manufacturing.
Each annex focuses on a different specific topic, such as the manufacture of sterile products, procedures for certain technological applications, or the examination of specific quality aspects. These annexes help manufacturers better understand and address the unique challenges and requirements in various areas. Currently, there are annexes available from Annex 1 to Annex 20.

EU-GMP Annex 11 – Computerized Systems

The annex has been revised to address the increased use and growing complexity of computerized systems employed in GMP-regulated operations. Such systems comprise software and hardware components working together to fulfill specific functions. They must be validated, and the IT infrastructure qualified. When manual activities are replaced by computerized systems, product quality, process control, and quality assurance must not be compromised, nor should the overall risk of the process increase.

EU-GMP Annex 15 – Qualification and Validation

This document provides guidance on the interpretation of GMP principles for human and veterinary medicinal products according to Directives 2003/94/EC and 91/412/EEC. It describes the qualification and validation of facilities, equipment, utilities, and processes in drug manufacturing, and it can optionally be applied to active substances without imposing additional requirements. Manufacturers must control critical aspects throughout the entire product and process lifecycle through qualification and validation. Changes that affect product quality should be documented, and their impact on the validation status should be assessed. Computerized systems must be validated in accordance with Annex 11, taking into consideration the guidelines ICH Q8, Q9, Q10, and Q11.

EU-GMP Annex 20 – Quality Risk Management (QRM)

Annex 20 of the EU GMP Guidelines, which aligns with the ICH Q9 Guideline, provides guidance for systematic Quality Risk Management (QRM). It aids in ensuring compliance with GMP requirements and other quality standards by providing principles and methods for formal quality risk management.

EU-GMP Guidelines

The European Commission has set forth requirements for quality assurance in production processes and environments in the principles of Good Manufacturing

Practice (GMP) for medicinal products for human use to ensure process verification. Detailed guidelines for interpreting these GMP principles can be found in the EU GMP Guide:

- EU GMP Guide Part I: Guide to Good Manufacturing Practice.
- EU GMP Guide Part II: Basic requirements for active substances used as starting materials.
- EU GMP Guide Part III : GMP-related documents.
- EU GMP Guide Part IV: GMP requirements for advanced therapy medicinal products.

F

FAT – Factory-Acceptance-Test

The Factory Acceptance Test (FAT) is an inspection and approval process for a product at the manufacturer‘s facility before it is delivered to the customer. The goal of the FAT is to verify the functionality and quality of the equipment under controlled conditions to ensure it meets the specified requirements. Following delivery to the customer, a Site Acceptance Test (SAT) is typically conducted, which tests the product at the customer‘s final location to verify proper installation and operational readiness. These tests are critical steps in the quality management process to ensure that the product meets the requirements and functions reliably.

FDA – 482

The FDA can inspect a facility for various reasons, such as routine investigations, surveys, or in response to reported issues. Upon arrival at the site, the investigator will present their credentials and the inspection form (FDA Form 482).
https://www.fda.gov/industry/fda-basics-industry/what-should-i-expect-during-inspection

FDA – 483

FDA Form 483 is used to document deficiencies observed during an FDA inspection. The investigator presents it during the closing meeting of the inspection. After being issued, the form is also sent to the responsible district office, which is in charge of evaluating the inspection. Depending on the significance of the noted deficiencies, a Warning Letter may follow as the next regulatory action. Issued FDA 483 documents are also made publicly available on the FDA‘s website.
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations

FDA – Food and Drug Administration

The FDA (Food and Drug Administration) is an agency of the U.S. Department of Health and Human Services responsible for regulating and overseeing foods, pharmaceutical drugs, medical devices, vaccines, biological products, cosmetics, and tobacco products. It ensures that these products are safe, effective, and properly labeled. Additionally, the FDA is responsible for the approval and control of these products, as well as imported goods that fall under its jurisdiction.

FDA – Warning Letter

An FDA Warning Letter is a formal notification from the U.S. Food and Drug Administration (FDA) sent to companies that have violated legal or regulatory requirements. The letter highlights specific violations identified during an inspection or review and demands that the company address the issues promptly. Receiving such a letter is serious, as failure to comply with the stipulated timeframe for correcting the deficiencies could lead to the denial of an approval or a complete import halt. Warning Letters are publicly accessible on the FDA‘s website.
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters

FDA – Guidance for Industry – Process Validation

This guideline summarizes the principles and approaches recommended by the FDA for process validation in the manufacture of drugs and biological products for humans and animals. It incorporates best practices that manufacturers can use to validate their production processes and aligns these with the product lifecycle concept and existing FDA and ICH guidelines.

Fh-Value

$$\mathrm{Fh} = \Delta t \sum 10^{\frac{T-170}{z}}$$

The Fh value, often referred to as the heat penetration factor in the context of dry heat sterilization, is an important parameter for evaluating the efficiency and effectiveness of the sterilization process. Unlike moist heat sterilization, which typically uses steam at 121.1°C, dry heat sterilization employs higher temperatures. The Fh value quantifies the time and temperature necessary to achieve a specific level of microbial reduction under these conditions.

FMEA – Failure Mode and Effects Analysis

FMEA, or Failure Mode and Effects Analysis, is a systematic method for identifying and evaluating potential failures in a product or process and their effects before they occur. It helps identify risks to implement proactive measures for risk mitigation. The analysis assesses the severity of potential failures, the likelihood of their occurrence, and the detectability of these failures. This methodology is widely used in quality management, especially in areas that must meet high safety and reliability requirements.

FMECA – Failure Mode, Effects, and Criticality Analysis

The methodical approach you‘re referring to is FMECA, which stands for Failure Mode, Effects, and Criticality Analysis. This process builds on FMEA by not only identifying potential failure modes and their effects but also assessing the criticality of these failure modes. The criticality analysis helps prioritize risks based on their severity, occurrence, and detectability, allowing teams to implement more focused and effective risk mitigation strategies.

F_0-Value

The F_0 value is a measure of the effectiveness of steam sterilization, defined as the time in minutes required at 121.1°C to destroy all microorganisms, considering a specified Z-value. This concept is critical in ensuring that sterilization processes are thorough and consistent, maintaining the safety and efficacy of products, particularly in industries such as pharmaceuticals and medical technology.

$$F0 = \Delta t \sum 10^{\frac{T\text{-}121.1}{z}}$$

FTA – Fault Tree Analysis

is a methodological technique for identifying and analyzing the various factors that can lead to a specific failure event in a system.

G

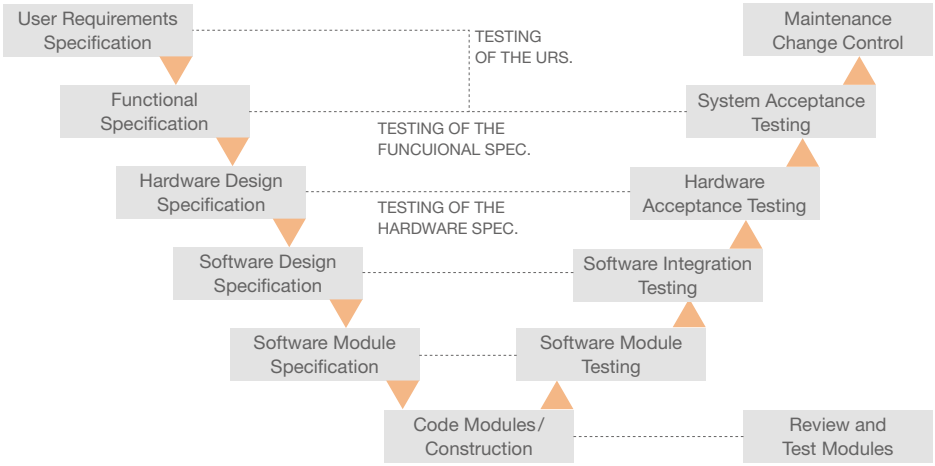
GAMP® – Good Automated Manufacturing Practice

The GAMP® guide, first published in 1994 by the Pharmaceutical Industry Computer Systems Validation Forum (now the GAMP® Forum) in collaboration

with the ISPE®, has become a standard for the validation of computerized systems in the pharmaceutical industry. Although it is not legally binding and alternative validation approaches are possible, it serves as an important guideline for manufacturers and suppliers.

GAMP® 5V-Model

GAMP® 5 is a guideline for the validation of automated systems in the pharmaceutical industry. The V-Model represents the development and validation process in a V-shape, with each development phase on the left side corresponding to a specific test phase on the right side. This model helps ensure that systems are thoroughly tested and regulatory standards are met. By following a sequential approach, it ensures that all documentation and validation steps are completed in a logical order. Responsibilities and accountabilities between suppliers and clients can also be defined within the V-Model. In doing so, it captures not only technical but also organizational aspects, which facilitates collaboration among the parties involved in a project.



GCP – Good Clinical Practice

GCP, or Good Clinical Practice, encompasses internationally recognized guidelines that set ethical and scientific standards for the planning and conduct of clinical trials. These guidelines ensure that the rights, safety, and well-being of trial participants are protected and that the data collected during the trials are credible and accurate.

GDP – Good Distribution Practice

Includes measures and guidelines that are important for the proper distribution of pharmaceutical products. These practices are designed to maintain the quality and integrity of medicinal products as they are transported through the supply chain. GDP covers aspects such as storage, transportation, traceability, and quality risk management. The goal is to ensure that the products arrive safely, effectively, and intact to the end consumers.

GEP – Good Engineering Practice

Good Engineering Practice includes a set of standards and procedures applied in the planning, design, implementation, and maintenance of engineering systems and projects. These practices aim to ensure that all technical solutions and facilities operate efficiently, safely, and in compliance with regulatory requirements.

GLP – Good Laboratory Practice

Good Laboratory Practice is a set of regulations that specifies requirements for the organization, planning, and conduct of non-clinical studies involving substances and pharmaceuticals. It also includes the documentation of results and quality control of these tests.

GMP – Good Manufacturing Practice / cGMP – Current Good Manufacturing Practice

GMP – Good Manufacturing Practice, and its more current iteration, cGMP – current Good Manufacturing Practice, describe guidelines and regulations designed to ensure a consistently high product quality of pharmaceuticals and active ingredients. These practices encompass various aspects of production, such as quality management, manufacturing processes, and facility maintenance, to ensure safety, efficacy, and compliance with regulatory standards.

GSP – Good Storage Practices

Good Storage Practices involve standards and guidelines aimed at storing products safely, efficiently, and in a manner that preserves their quality. These practices ensure that storage conditions, such as temperature and humidity, are appropriately controlled to maintain the integrity and effectiveness of products.

GxP / cGxP

GxP stands for „Good x Practice“ and is a general term that refers to various quality guidelines and regulations applied in regulated industries such as the

pharmaceutical, food, and medical device sectors. The „x“ in GxP can be replaced by different letters to cover various areas:

- GLP: Good Laboratory Practice – related to the quality and integrity of laboratory data results.
- GMP: Good Manufacturing Practice – related to quality assurance during production.
- GDP: Good Distribution Practice – refers to the proper storage and transportation of products.
- GCP: Good Clinical Practice – related to the ethical and scientific standards for clinical trials.
- GEP: Good Engineering Practice – pertains to the established practices in technical projects.

H

HACCP – Hazard Analysis and Critical Control Points

HACCP is a proactive risk management system designed to ensure the safety of food and pharmaceutical products. The HACCP system identifies potential hazards in a production process and establishes critical control points where actions can be taken to minimize or eliminate these hazards.

HAZOP – Hazard and Operability Study

This method is a systematic approach to identifying potential risks and vulnerabilities in industrial processes, particularly in the chemical and pharmaceutical industries. HAZOP studies are conducted to detect deviations from the intended operational mode that could lead to hazards, and to assess their impact on safety, efficiency, and quality. The procedure involves the structured analysis of processes using „Guide Words“ to identify potential hazard points and faulty operating conditions.

I

ICH – International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use

The ICH, originally the „International Conference on Harmonization,“ was established in 1990 by the FDA, the European Commission, the Japanese

Ministry of Health, and major pharmaceutical industry associations. Based in Geneva, the ICH develops standardized guidelines for the quality, efficacy, and safety of pharmaceuticals, such as GCP or GMP. These guidelines serve as directives for the pharmaceutical industry. Observers include the WHO (World Health Organization) and EFTA (European Free Trade Association). In the EU, the guidelines are adopted by the EMA (European Medicines Agency) and are considered standards from which pharmaceutical companies should deviate only in exceptional cases.

ICH Q9 – Quality Risk Management – Scientific Guideline

This document provides principles and examples of quality risk management that can be applied to various aspects of quality assurance measures. These include development, manufacturing, distribution, as well as inspection and submission/review processes throughout the lifecycle of active substances, pharmaceuticals, and biological and biotechnological products. In summary, the document contains guidelines and tools for quality risk management that are applicable throughout the entire value chain of pharmaceutical products.

IQ – Installation Qualification

This phase of the validation process is conducted to ensure that equipment, systems, or facilities are installed correctly and meet all technical specifications, manufacturer requirements, and regulatory standards. This includes, among other things, the acceptance of proper electrical installation, the detailed review of all input and output signals, and the correct calculation of measured value.

ISPE® GAMP® 5 – A Risk-Based Approach to Compliant GxP Computerized Systems

GAMP® 5 (Good Automated Manufacturing Practice) is a guide used in the implementation and validation of computerized systems in the pharmaceutical industry. It provides a risk-based approach to ensure that all automated systems operate in compliance with applicable regulatory requirements and ensure the intended product quality and data integrity. GAMP® 5 emphasizes the importance of a lifecycle approach to system validation, taking into account project planning, specification, verification, and maintenance.

ISPE® – International Society for Pharmaceutical Engineering

The International Society for Pharmaceutical Engineering is a non-profit organization that promotes scientific, technical, and regulatory advancements

in the pharmaceutical industry. It supports its members through knowledge exchange, training, and resources related to engineering and regulated processes and is involved in the development of standards and regulations.

J

JP – Japanese Pharmacopeia

The Japanese Pharmacopoeia (JP) provides standards for the quality, safety, and efficacy of pharmaceuticals in Japan. It contains mandatory norms for the manufacturing, testing, and use of pharmaceutical products.

K

L

LVP – Large Volume Parenteral

Large Volume Parenteral (LVPs) are sterile pharmaceutical products packaged in containers holding more than 100 ml. These products are primarily used for the intravenous administration of fluids containing electrolytes, nutrients, or medications. LVPs undergo rigorous sterilization processes, or aseptic filtration, to ensure their safety and efficacy.

M

N

O

OOE – Out-of-Expectation

Out of Expectation“ (OOE) results are findings that prove to be singular anomalies and, statistically speaking, do not carry significant meaning. They generally do not indicate a systemic issue. OOE results are typically atypical or divergent findings that do not align with other existing data. In contrast to an „Out of Specification“ (OOS) result, OOE findings do not violate established specification limits.

OOS – Out-of-Specification

Out of Specification (OOS) refers to test results that fall outside the established acceptance criteria, as defined in official pharmacopeias or company-specific documents. The term is primarily used in the context of FDA regulations. OOS results are test findings that do not meet specified standards. Addressing such deviations is an essential part of quality assurance systems like ISO 9001, GMP, and GLP.

OOT – Out-of-Trend

OOT describes a result that falls within the specified limits but shows a trend that is noticeable in the statistical evaluation. Such results are often referred to as „Out of Trend“ (OOT). An OOT result indicates that while the results are still within established specifications, there is a trend or change over time that requires attention. Such trends can be important for early identification of potential issues and ensuring that processes remain stable.

OQ – Operational Qualification

OQ, or Operational Qualification, is a critical step in the validation process of equipment and systems within regulated industries, such as the pharmaceutical and medical technology sectors. It verifies and documents that all equipment, systems, or processes operate correctly within their intended environment and across their entire operational range. During the OQ phase, specific test protocols and procedures are conducted to ensure that all operational parameters meet the established specifications.

P

PAT – Process Analytical Technology

In the pharmaceutical and biotechnology industries, Process Analytical Technology (PAT) refers to a system for analyzing and controlling manufacturing processes through real-time measurements of critical quality attributes (CQAs) of the product. The goal of PAT is to achieve a better understanding and control of manufacturing processes to optimize product quality while reducing production costs and times.

PCS – Process Control System

A process control system is an integrated system of technologies and procedures used to monitor and control production processes. It ensures that these processes

run efficiently, safely, and within specified parameters. In pharmaceutical manufacturing, a PCS is used to ensure that both intermediate and finished products, such as active pharmaceutical ingredients (APIs), meet specifications and quality standards.

PDA® Parenteral Drug Association

The Parenteral Drug Association (PDA®) is an international organization focused on advancing science and regulation in the pharmaceutical and biotechnology industries. It supports professionals in these fields by providing education, expertise, and guidelines to improve the quality and safety of parenteral (i.e., non-orally administered) drugs and related products. The PDA® is well known for its role in developing Best Practices and standards. Its Technical Reports offer practical guidance for a wide range of applications and are often referenced in standards and regulations.

PHA – Preliminary Hazard Analysis

This method is an early form of risk analysis used during the planning phase of a project or the introduction of new processes and products. The goal of Preliminary Hazard Analysis (PHA) is to identify potential hazards and assess risks before the design is finalized. The analysis considers possible events that could lead to hazards, their impacts, and possible risk mitigation measures.

PIC/S® – Pharmaceutical Inspection Cooperation Scheme

The Pharmaceutical Inspection Co-operation Scheme (PIC/S®) is an international cooperative program originally established as a successor to the Pharmaceutical Inspection Convention. The goal of PIC/S® is to promote cooperation and harmonization among Good Manufacturing Practice (GMP) supervisory authorities worldwide. This is achieved by standardizing inspection processes and improving communication between regulatory bodies and the pharmaceutical industry. By publishing guidelines and recommendations, PIC/S® helps ensure the manufacture and safety of pharmaceutical products on a global level. The comprehensive standards provided by PIC/S® assist in improving quality assurance and help avoid so-called multiple inspections.

PPQ Process Performance Qualification

Process Performance Qualification (PPQ) is a critical step in Process Validation, specifically in the second phase known as Process Qualification. It extends beyond Performance Qualification by assessing the long-term performance and

robustness of the manufacturing process. According to GAMP® 5, PPQ expands the qualification of a facility for producing medical and pharmaceutical products after the completion of Performance Qualification.

PQ – Performance Qualification

Performance Qualification (PQ) is the documented verification that facilities, systems, and equipment operate efficiently and with repeatable performance in accordance with approved requirements. It includes testing under real conditions, confirmation of compliance with quality standards, evaluation of the reproducibility of results, as well as meticulous data documentation and analysis.

PQR – Product Quality Review

Product Quality Review (PQR) is a legally required, periodic assessment that ensures pharmaceutical products are consistently manufactured and controlled according to cGMP requirements for quality, safety, and efficacy standards. In addition to retrospective analysis, the PQR also serves real-time process control and continuous improvement by providing a comprehensive view of all relevant data. By applying statistical tools, deviations are predicted and trends are identified, allowing for corrective and preventive actions to be taken if necessary. The frequency of conducting the review is based, among other factors, on historical review results but should be conducted at least once annually.

Predictive Maintenance

This method utilizes advanced technologies for real-time monitoring and data analysis to predict when maintenance is required. This allows for the detection of potential failures and the execution of maintenance only when necessary, extending equipment lifespan and reducing downtime and maintenance costs. An example of this is continuous monitoring systems such as the Kaye LabWatch System.

Preventive Maintenance

Preventive maintenance involves scheduled maintenance activities that are carried out regardless of the equipment‘s condition. The goal is to prevent failures and extend the lifespan of the assets. This proactive approach helps ensure that equipment operates efficiently and reliably, reducing unexpected downtime and potentially costly repair.

Prospective Validation or Premarket Validation

Prospective validation involves validation activities conducted before a product is routinely manufactured and released for sale. The goal is to ensure that a process or system meets the required quality, safety, and efficacy standards before commercial use. This process includes the planning, execution, and documentation of tests to comply with regulatory requirements.

PS – Purified Steam

Purified steam is steam that meets the stringent purity criteria to qualify as Water for Injection (WFI) once it is condensed. In the pharmaceutical industry, clean steam is primarily used for the sterilization of components that come into contact with products. Additionally, it is used to humidify air supplies in cleanrooms and isolators to ensure a controlled and sterile environment.

PW – Purified Water

Purified water is water that has been freed from chemical and microbiological impurities through various processes, such as distillation, reverse osmosis, or ion exchange. It is primarily used in the pharmaceutical industry, where high purity requirements exist but sterility or pyrogen-free conditions are not necessary. Purified water is used in the manufacturing of non-injectable pharmaceuticals, as a solvent, or as a base for the production of products like dialysis solutions, provided it meets certain purity requirements, such as the endotoxin test according to pharmacopeial standards.

PV – Process Validation

Process validation is a step-by-step and documented procedure to ensure that processes, within their established design parameters, are capable of consistently producing a final product of the required quality. The extent of the validation is largely determined by a previously conducted risk analysis. The greater the risk, the higher the validation effort required.

Q

QA – Quality Assurance

Quality Assurance (QA) is a systematic process focused on monitoring and improving quality standards in the manufacturing (process focused) and delivery of products or services. In the pharmaceutical industry, QA ensures that all products

meet the required quality standards and regulatory requirements, from the verification of raw material quality to the comprehensive testing of final products.

QbD – Quality-by- Design

The European Medicines Agency (EMA) supports the application of Quality by Design (QbD) to optimize pharmaceutical manufacturing. This approach ensures the quality of pharmaceuticals through statistical and analytical methods as well as risk management. It involves identifying and controlling sources of variability to ensure that medications meet predefined characteristics right from the start. The concept utilizes multivariate analyses and modern tools to better understand critical attributes and production parameters, enabling continuous improvements.

QC – Quality Control

Quality Control (QC) is a systematic process in the manufacturing industry focused on ensuring that products (Product focused) meet established quality standards. QC involves the testing and inspection of products at various stages of production to ensure they conform to specifications and are free from defects. This process includes identifying and correcting defects, as well as verifying compliance with regulations and standards.

QMS – Quality Management System

A Quality Management System (QMS) in the context of Good Manufacturing Practice (GMP) is a structured system of procedures, processes, and resources designed to ensure the quality and safety of pharmaceutical products throughout the entire production process. It encompasses all elements of quality management, including planning, control, quality assurance, and continuous improvement, to comply with regulatory requirements and to ensure the efficacy and safety of medications.

QP – Qualification Protocol

A Qualification Protocol (QP) is a written plan or procedure that details how qualification is to be achieved. It includes specific qualification requirements for each piece of equipment, system requirement, and product requirement.

QP – Qualified Person

The Qualified Person in pharmacy has a key role in European pharmaceutical law, responsible for the manufacturing, testing, and release of medicinal products in accordance with regulations. They also ensure complete documentation of

compliance with legal requirements.

QSM – Quality System Manual

A Quality System Manual is a comprehensive document that outlines the structure, processes, and policies of a company‘s Quality Management System (QMS). It sets the standards and procedures designed to ensure that products and services meet the required quality requirements. The manual serves as a guide for all employees to achieve the company’s quality objectives and ensure compliance with legal and industry-specific requirements.

Qualification

The term „qualification“ in the GxP environment refers to the process of verifying the suitability of a device, facility, or system for its intended purpose. The first mention of „qualification“ in GxP regulations is hard to pinpoint, but it is traced back to the late 1970s when the FDA introduced validation as part of Good Manufacturing Practice (GMP). This process includes Design, Installation, Operational, and Performance Qualifications (DQ, IQ, OQ, PQ). The exact qualification process may vary depending on the context and specific device or system. Qualification is divided into individual executable steps. It is a component of validation and relates to the performance and characteristics of systems, equipment, instruments, facilities, and software. It typically includes the following steps:

- **URS (User Requirement Specification):** Document that captures and defines the requirements for a specific system or product.
- **DQ (Design Qualification):** Verification process that confirms the design of the equipment or system meets all predefined requirements for the intended purpose.
- **FAT/SAT (Factory Acceptance Test/Site Acceptance Test):** FAT is a pre-shipment test process conducted at the manufacturer‘s site to confirm the design and operational compliance of the system. SAT validates the correct installation and functional performance of the system at the customer‘s site before full operation commenced.
- **IQ (Installation Qualification):** Verification that the equipment or system is installed correctly and functions within the planned parameters in the intended environment.
- **OQ (Operational Qualification):** Verification that the equipment or system operates as intended throughout the entire operational range in its specific environment.

- **PQ (Performance Qualification):** Confirmation and documentation that the equipment or system can consistently perform according to the parameters defined in the URS (User Requirement Specifications)

R

Retrospective Validation

Retrospective validation involves reviewing and analyzing existing production data and batch records to evaluate the consistency and performance of an already utilized process. The goal is to determine if the process consistently produced products with the desired quality attributes and meets quality and regulatory standards based on historical data.

Revalidation

Revalidation is the process of re-assessing and repeating validation activities to ensure that systems, processes, or equipment continue to meet established quality and performance standards. It involves analyzing existing performance data and is crucial for maintaining the validated status, particularly when significant changes occur or to ensure ongoing compliance with regulatory requirements.

Risk Acceptance

Risk Acceptance refers to the willingness to accept risk, either formally or passively. Even with good risk management practices, not all risks can be eliminated. Therefore, risk is often reduced to a specified, acceptable level that is determined based on the situation.

Risk Analysis

Risk analysis is the assessment of the risk associated with identified hazards. It is the qualitative or quantitative process of linking the likelihood of occurrence with the severity of potential harm. In some risk management tools, the ability to detect the harm (detectability) also plays a role in the assessment of risk.

Risk Assessment

Assessment of the occurrence of an identified risk and evaluation of its likelihood and impact. General questions to consider:

- What could go wrong?
- How likely is it going wrong?
- What are the consequences (severity)?

Risk Communication

Exchange of information about risks and risk management among all departments involved in the process, including quality control, quality management, and executive management.

Risk Control

Establishing risk acceptance criteria, risk reduction, and risk acceptance. Risk control involves making decisions to reduce and/or accept risks. The goal of risk control is to lower the risk to an acceptable level. The effort for risk control should be proportional to the significance of the risk.

Risk control might focus on the following questions:

- Is the risk above an acceptable level?
- What can be done to reduce or eliminate risks?
- What is the appropriate balance between benefits, risks, and resources?
- Are new risks being introduced as identified risks controlled?

Risk Evaluation

Risk assessment compares identified and analyzed risks with established risk criteria.

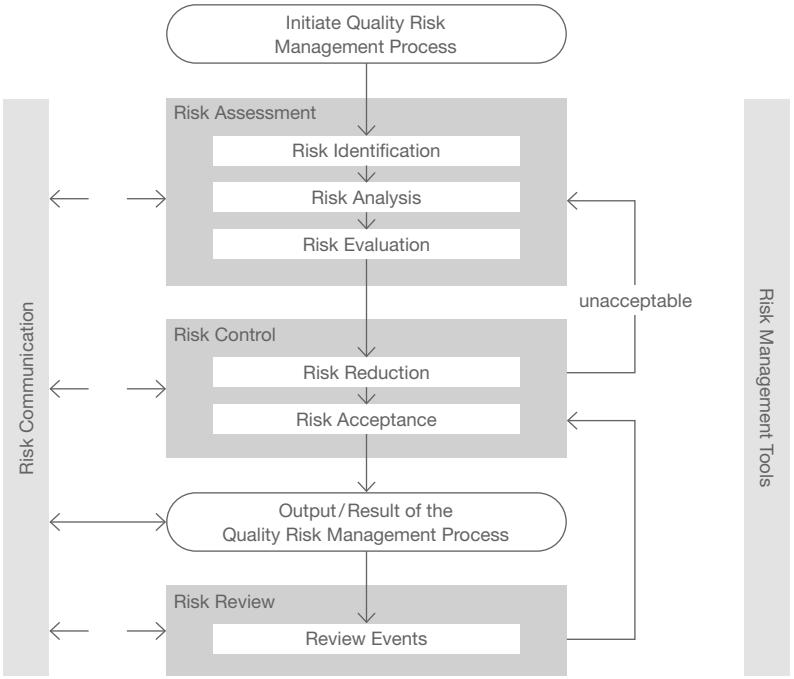
Risk Identification

Identifying, capturing, and documenting potential risks that could impact quality, and safety is a critical component of effective risk management. This process involves systematically evaluating possible sources of risk in order to implement appropriate mitigation strategies.

Risk Management

Risk management is a central component in the GxP environment throughout the entire lifecycle of a facility/process/system/instrument and is part of guidelines and regulations. The risk management process aims to ensure that all risks are identified, assessed, and adequately controlled to guarantee the quality and safety of pharmaceutical products. The five fundamental steps of risk management are:

- Risk Identification
- Risk Assessment
- Risk Control
- Risk Communication
- Risk Review



Overview of a typical quality risk management process

Risk Management Tools

Quality risk management provides scientific and practical methods for decision-making in risk management, based on the assessment of the probability, severity, and detectability of risks. Traditional and modern risk management tools can be applied in combination to offer flexibility. These methods are adapted to the complexity and criticality of the issues to be addressed. A range of tools such as FMEA, FTA, HACCP, PHA, and HAZOP support this process.

Risk Reduction

Risk reduction involves actions to decrease or avoid quality risks when they exceed an acceptable level. While measures help reduce the severity and likelihood of harm and improve detectability, they can also introduce new risks or influence existing ones. Therefore, the risk assessment should be reviewed after the implementation of risk mitigation measures.

Risk Review

Refers to the regular review and evaluation of the risk management process and its

results to ensure that it remains current and effective. Risk management should be continuously integrated into the quality management process, with mechanisms for monitoring and ongoing evaluation. The results should be regularly reviewed and adjusted to incorporate new knowledge. Changes, such as scheduled inspections or unscheduled recalls, should be incorporated into the process based on the outcomes of the risk review.

S

SAL – Sterility Assurance Level

The Sterility Assurance Level, also known as SAL, describes the probability that a single product remains contaminated after the sterilization process. This metric is primarily used in the manufacturing of sterile pharmaceuticals and medical devices.

Sanitization

Sanitization is a multi-step process and can typically be divided into several common stages:

1. Preparation: Removal of unnecessary material and provision of cleaning and disinfecting agents.
2. Cleaning: Thorough removal of dirt and organic materials from surfaces.
3. Rinsing: Removal of cleaning agent residues by thorough rinsing.
4. Disinfection: Application of disinfectants to kill remaining microorganisms; in cold sanitization, chemical agents are used at low temperatures.
5. Inspection and Documentation: Verification of the sanitization process and documentation of all measures to ensure hygiene standards.

The differences between hot and cold sanitization lie in the temperature range and the method of microorganism reduction:

- Hot sanitization uses temperatures between 80-90°C, such as hot water or steam, to kill bacteria, viruses, and fungi, but it is energy-intensive and can cause material wear.
- Cold sanitization uses chemical agents at low temperatures, ideal for temperature-sensitive materials, but requires careful selection and handling of chemicals.

SAT – Site-Acceptance-Test

A Site Acceptance Test (SAT) is a critical testing process that ensures a machine or

system is properly installed, configured, and operational at the customer‘s site. It assesses whether the equipment meets operational requirements and documents the current state to record deviations from specifications. The process includes verifying the installation, the functionality of components, compliance with safety standards, and performance testing to ensure quality and safety before regular operation is commenced.

SIP – Steam in Place

Steam-in-Place (SIP) sterilization is a critical process in the pharmaceutical industry to ensure the sterility of permanently installed systems such as tanks, pipelines, and bioreactors in aseptic manufacturing. This process uses saturated steam to kill microorganisms without requiring the disassembly of equipment. The same standards and regulations applied to steam autoclaves/steam sterilizers are used in SIP. Relevant standards for moist heat sterilization, such as EN 285 or ISO 17665, are considered. Typically, the CIP (Clean-In-Place) process precedes the SIP process, preparing the equipment for sterilization.

SMF – Site Master File

A Site Master File (SMF) is a central part of the documentation in pharmaceutical manufacturing, containing information about a production site and its facilities. It is created by the pharmaceutical manufacturer to ensure compliance with Good Manufacturing Practice (GMP) and regulatory standards. The SMF includes site details, personnel qualifications, production processes, quality control systems, distribution and transportation conditions, and certifications. It serves as an essential document for regulatory authorities, customer assessments, and inspections.

SOP – Standard Operation Procedure

Documented work instructions that detail regularly performed processes and tasks. These instructions serve to ensure consistency and quality in the execution of processes. Standard Operating Procedures (SOPs) are critical to ensure all employees adhere to required standards and regulations, thereby maintaining product quality, safety, and regulatory compliance.

Steam Quality

In steam sterilization, steam quality refers to the specific properties of steam required for successful sterilization. It defines the mass ratio of steam to water in a steam-water mixture.

The following steam properties are significant for sterilization:

- High energy content for optimal heat transfer and reaching sterilization temperatures.
- Increased penetration ability to ensure complete coverage of the items to be sterilized.
- Ability to condense and displace air from the chamber, facilitating effective sterilization.

Poor steam quality can impair sterilization, as both heat transfer and steam penetration may be hindered. Therefore, monitoring and controlling steam quality in moist heat sterilization are crucial.

SVPs – Small Volume Parenteral

Small Volume Parenteral (SVPs) refer to sterile injection solutions typically packaged in volumes of less than 100 ml. These solutions are packaged in various containers depending on their intended use. SVPs are commonly used for the administration of medications and must meet stringent sterilization requirements.

T

Temperature (Heat) Penetration Study

The purpose of a temperature penetration study is to determine the heating and cooling characteristics of a product/package combination in a specific sterilization process in order to establish safe thermal processes and evaluate process deviations. The study must be designed to adequately and accurately investigate all critical factors affecting heating rates associated with the product, packaging, and process. Penetration studies are often conducted in parallel with temperature distribution studies.

Temperature Mapping Study

Temperature distribution studies are applied in various GMP areas as well as in different guidelines and standards. They are conducted wherever temperature is critical to process quality and ultimately the quality of the end product. This includes sterilization processes, cooling and freezing systems, storage rooms, stability chambers, and transport containers within the cold chain. For example, in a steam autoclave, the so-called cold spot and hot spot are determined,

while temperature mapping in a storage room supports, among other things, the placement of fixed monitoring sensors.

Traceability

Traceability generally means being able to track all steps of a product or process of a batch or actions taken from the origin of raw materials to the final distribution of the finished product. For example, traceability in the calibration of a temperature sensor means that the calibration and adjustment can be traced back to a national temperature standard.

U

URS – User-Requirements-Specifications

This is a document that describes the client‘s requirements and expectations for a new product or system. It outlines what the system should accomplish and, together with technical and regulatory requirements, forms the basis for the specifications document. The specifications document is usually created by the customer or client.
This document is a component of the V-Model. It consolidates requirements from various sources and supports the design, commissioning, qualification, as well as the operation and maintenance of a system. Critical quality attributes and process parameters are important components that need to be identified to support the quality risk-based process. The specifications can be flexibly designed to meet the needs of a multipurpose operation and are dynamic documents that are updated when changes occur.

USP® – United States Pharmacopeia

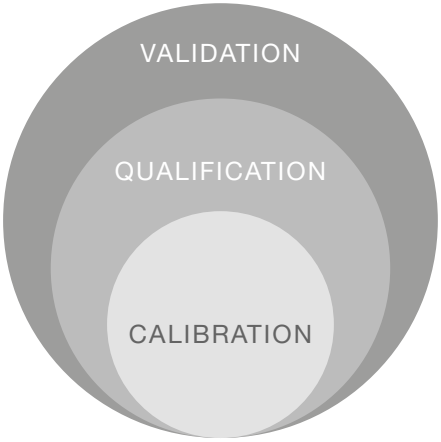
The United States Pharmacopeia (USP®) is an American non-profit organization that develops standards for the quality assurance of medicines and dietary supplements. These standards are important for regulatory compliance in the pharmaceutical industry worldwide.

V

Validation

Validation is the documented process of verifying that a system, process,

equipment, or product reliably meets the specific requirements and quality standards. This process ensures that all critical parameters are controlled and consistently produce reproducible results to guarantee both the safety and effectiveness of the final product. Thus, validation is the documented evidence that all procedures, processes, facilities, systems, materials, and equipment comply with GxP requirements and deliver the expected results.



Validation Matrix

Especially in complex validations, the validation matrix facilitates oversight. It is a structured document or tool that represents the relationship between various validation requirements and the elements to be validated, such as systems, processes, or equipment. This matrix helps ensure that all aspects of a project comply with regulatory and internal company standards.

Typically, a validation matrix includes information on:

- Validation Requirements: Specific criteria that need to be met based on regulatory guidelines and company standards.
- Elements to be Validated: Listing of the systems, processes, or components that need to be validated.
- Tests and Criteria: Methods and procedures applied to confirm the fulfillment of the requirements.
- Documentation: References to the documents that contain the results and evidence of the validation.

- Responsibilities: Assignment of tasks to specific individuals or teams for conducting validation activities.

Validation Plan

Validation planning is an essential process in quality assurance, where it is verified that a system or product meets the established requirements. To achieve this, specific tests and inspections are planned and documented. In addition to planning, a risk analysis is often necessary to identify potential weaknesses and develop targeted validation measures to mitigate risks.
In many industries, particularly in pharmaceuticals, medical, and food industries, compliance with regulatory requirements drives validation planning. It is crucial that all tests and inspections comply with these regulations to ensure compliance. Thorough documentation of the validation process is vital to demonstrate adherence to quality requirements, especially during audits or inspections.

Validation Protocol

A validation protocol is a detailed, written summary that describes specific tests and procedures to verify whether a product meets the requirements for its intended purpose. It includes instructions for conducting the validation, acceptance criteria, and the necessary documentation of the results. The protocol is more focused than the validation plan and concentrates on the practical implementation of validation for specific processes or products.

Validation Report

After the validation activities are completed, the validation report documents the results and evaluates whether the validation requirements have been met. The report includes the analysis and interpretation of the data, indicates whether the acceptance criteria were achieved, and provides recommendations for future actions.

VMP – Validation Master Plan

The Validation Master Plan (VMP) is a strategic document that guides all validation activities of a manufacturing facility to ensure consistent product quality and compliance with quality standards. As an essential element of a company's quality commitment, the VMP ensures that products and processes are systematically validated. It supports consistency and control in production, minimizes risks, and ensures regulatory compliance through detailed documentation and alignment with current regulations. Additionally, the VMP optimizes resource utilization and

provides clear instructions for error minimization. It must comply with applicable regulatory requirements, such as those from the FDA and the EU. In general, the VMP establishes a company's validation strategy and defines and documents the intentions, responsibilities, approaches, and key aspects of a validation program.

W

WFI – Water-for-Injection

Water for Injection (WFI) is a highly purified form of water specifically used in the production of pharmaceuticals for parenteral administration. It serves as a carrier material for dissolving or diluting substances or preparations intended for injection into the body. WFI must meet stringent quality requirements to ensure it is free from impurities and microbiological contamination. In the pharmaceutical industry, it is an essential component in ensuring the safety and efficacy of injectable preparations.

WHO – World Health Organization

The World Health Organization (WHO), founded in 1948 and headquartered in Geneva, serves as the coordinating authority for international public health matters. Its goal is to create a better and healthier future for people worldwide.

WIP – Washing-in-Place

WIP (Washing In Place) refers to the semi-automated cleaning and disinfection of e.g. filling machines by pumping appropriate cleaning and disinfecting agents into the system. Unlike CIP (Cleaning-In-Place), WIP requires additional manual cleaning effort.

X

Y

Z

ZLG – Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

The Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und

Medizinprodukten (ZLG) is a German institution that coordinates cooperation between the federal states on health protection issues. It plays an important role in the harmonization and monitoring of standards for medicinal products and medical devices in Germany. The ZLG supports state authorities in the surveillance, approval, and certification of products and processes in the medical field to ensure safety and efficacy. Through this coordinated approach, the ZLG contributes to ensuring high-quality standards in health protection.

Z-Value

The Z-value is a microbiological parameter that characterizes the kill behavior of microorganisms during sterilization. It describes the necessary increase in temperature to reduce the D-value by a factor of ten, resulting in a log-cycle reduction of microorganisms. The Z-value indicates the sensitivity of microbes to temperature changes and is central to ensuring effective microorganism reduction with minimal impact on the product.

Important Standards and Guidelines

For more information, visit:
https://www.kayeinstruments.com/en/knowledge-library/norms-guidelines

Important Organizations and Regulatory Bodies

Explore further at:
https://www.kayeinstruments.com/en/knowledge-library/norms-guidelines#organizations

Kaye, a subsidiary of Amphenol, is a recognized leader in high accuracy thermal process management and monitoring. Primarily focused on pharmaceutical applications, Kaye technology is relied upon by the world's leading drug manufacturers to verify critical sterilization processes and monitoring environmental parameters as required by governing regulatory bodies. With over > 40.000 systems installed around the world, Kaye has become the standard for validating thermal processes and documenting the results and helping our clients to be compliant according current standards.

LOCATIONS

1. Pforzheim, Germany
2. St. Marys, PA, USA
3. Fremont, CA, USA
4. Billerica, MA, USA
5. Changzhou, China
6. Hyderabad, India

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