COMPILED REGULATORY GUIDELINES / REGULATIONS FOR THE PHARMACEUTICAL INDUSTRY	
Eudra Lex - Volume 4 - Good Manufacturing Practice (GMP) guidelines	
The rules governing medicinal products in the European Union" contains guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use.	
Part-I Basic requirements for Medicinal products	
Chapter-1	Pharmaceutical quality system
Chapter-2	Personnel
Chapter-3	Premises and equipment
Chapter-4	Documentation
Chapter-5	Production
Chapter-6	QC
Chapter-7	Contract Mfg and analysis
Chapter-8	Complaints and product recalls
Chapter-9	Self-inspection
Part-II Basic requirements for Active substances used as starting materials	
Part-III GMP related documents	
SMF, Q9,Q10,MRA batch certificate, Template for the "written confirmation" for active substances exported to the European Union for medicinal products for human use, guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities, guidelines of 19 March 2015 on the formalized risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use, template for IMP batch release.	
Annexure-1	Manufacture of Sterile medicinal products
Annexure-2	Manufacture of biological medicinal products for human use
Annexure-3	Manufacture of Radiopharmaceuticals
Annexure-4	Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products
Annexure-5	Manufacture of Immunological Veterinary Medicinal Products
Annexure-6	Manufacture of Medicinal Gases
Annexure-7	Manufacture of Herbal Medicinal Products
Annexure-8	Sampling of starting and packaging materials
Annexure-9	Manufacture of Liquids, Creams and Ointments
Annexure-10	Manufacture of Pressurized Metered Dose Aerosol Preparations for Inhalation
Annexure-11	Computerized Systems
Annexure-12	Use of Ionizing Radiation in the Manufacture of Medicinal Products
Annexure-13	Manufacture of investigational medicinal products
Annexure-14	Manufacture of Products derived from Human Blood or Human Plasma
Annexure-15	Qualification and validation
Annexure-16	Certification by a Qualified Person and Batch Release
Annexure-17	Parametric release
Annexure-19	Reference and retention samples
Part-IV GMP requirements for advanced therapy medicinal products	

Guidance for Industry Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) Office of Regulatory Affairs (ORA) September 2004 Pharmaceutical CGMPs	
I	Buildings and facilities
II	Personnel training, qualification, & monitoring
III	Components and container/closures
IV	Endotoxin control
V	Time limitations
VI	Validation of aseptic processing and sterilization
VII	Laboratory controls
VIII	Sterility testing
IX	Batch Record Review: Process Control Documentation
Appendix 1	Aseptic processing isolators
Appendix 2	Blow-fill- seal technology
Appendix 3	Processing prior to filling and sealing operations

CFR-Code of federal regulations

Is the codification of the general and permanent rules and regulations [sometimes called administrative law] published in the Federal Register by the executive departments and agencies of the federal government of the United States. The CFR is divided into 50 titles that represent broad areas subject to federal regulation.

Title 21 is the portion of the Code of Federal Regulations that governs food and drugs within the United States for the Food and Drug Administration [FDA], the Drug Enforcement Administration [DEA], and the Office of National Drug Control Policy [ONDCP]. It is divided into three chapters:

- Chapter I — Food and Drug Administration
- Chapter II — Drug Enforcement Administration
- Chapter III — Office of National Drug Control Policy.

Chapter I - Food and Drug Administration has Parts 1 to 1499.

Part 11-Electronic records, electronic signatures.
Subpart-A – General Provisions
- Scope
- Implementation
- Definitions

Subpart-B – Electronic Records
- Controls for closed systems
- Controls for open systems
- Signature manifestations
- Signature/record linking

Subpart-C – Electronic Signatures
- General requirements
- Electronic signatures and controls
- Controls for identification codes/passwords

Part 210-Current Good Manufacturing Practice for Finished Pharmaceuticals
§ 210.1 - Status of current good manufacturing practice regulations.
§ 210.2 - Applicability of current good manufacturing practice regulations.

Part 211-Current Good Manufacturing Practice for Finished Pharmaceuticals
Subpart A--General Provisions
§ 211.1 - Scope.
§ 211.3 - Definitions.
Subpart B--Organization and Personnel
§ 211.22 - Responsibilities of quality control unit.
§ 211.25 - Personnel qualifications.
§ 211.28 - Personnel responsibilities.
§ 211.34 - Consultants.
Subpart C--Buildings and Facilities
§ 211.42 - Design and construction features.
§ 211.44 - Lighting.
§ 211.46 - Ventilation, air filtration, air heating and cooling.
§ 211.48 - Plumbing.
§ 211.50 - Sewage and refuse.
§ 211.52 - Washing and toilet facilities.
§ 211.56 - Sanitation.
§ 211.58 - Maintenance.
Subpart D--Equipment
§ 211.63 - Equipment design, size, and location.
§ 211.65 - Equipment construction.
§ 211.67 - Equipment cleaning and maintenance.
§ 211.68 - Automatic, mechanical, and electronic equipment.
§ 211.72 - Filters.
Subpart E--Control of Components and Drug Product Containers and Closures
§ 211.80 - General requirements.
§ 211.82 - Receipt and storage of untested components, drug product containers, and closures.
§ 211.84 - Testing and approval or rejection of components, drug product containers, and closures.
§ 211.86 - Use of approved components, drug product containers, and closures.
§ 211.87 - Retesting of approved components, drug product containers, and closures.
§ 211.89 - Rejected components, drug product containers, and closures.
§ 211.94 - Drug product containers and closures.
Subpart F--Production and Process Controls
§ 211.100 - Written procedures; deviations.

§ 211.101 - Charge-in of components.
§ 211.103 - Calculation of yield.
§ 211.105 - Equipment identification.
§ 211.110 - Sampling and testing of in-process materials and drug products.
§ 211.111 - Time limitations on production.
§ 211.113 - Control of microbiological contamination.
§ 211.115 - Reprocessing.

Subpart G--Packaging and Labeling Control

§ 211.122 - Materials examination and usage criteria.
§ 211.125 - Labeling issuance.
§ 211.130 - Packaging and labeling operations.
§ 211.132 - Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.
§ 211.134 - Drug product inspection.
§ 211.137 - Expiration dating.

Subpart H--Holding and Distribution

§ 211.142 - Warehousing procedures.
§ 211.150 - Distribution procedures.

Subpart I--Laboratory Controls

§ 211.160 - General requirements.
§ 211.165 - Testing and release for distribution.
§ 211.166 - Stability testing.
§ 211.167 - Special testing requirements.
§ 211.170 - Reserve samples.
§ 211.173 - Laboratory animals.
§ 211.176 - Penicillin contamination.

Subpart J--Records and Reports

§ 211.180 - General requirements.
§ 211.182 - Equipment cleaning and use log.
§ 211.184 - Component, drug product container, closure, and labeling records.
§ 211.186 - Master production and control records.
§ 211.188 - Batch production and control records.
§ 211.192 - Production record review.
§ 211.194 - Laboratory records.
§ 211.196 - Distribution records.
§ 211.198 - Complaint files.

Subpart K--Returned and Salvaged Drug Products

§ 211.204 - Returned drug products.
§ 211.208 - Drug product salvaging.

Part 600-Biological products General.

Subpart A--General Provisions

§ 600.2 - Mailing addresses.
§ 600.3 - Definitions.

Subpart B--Establishment Standards

§ 600.10 - Personnel.
§ 600.11 - Physical establishment, equipment, animals, and care.
§ 600.12 - Records.
§ 600.13 - Retention samples.
§ 600.14 - Reporting of biological product deviations by licensed manufacturers.
§ 600.15 - Temperatures during shipment.

Subpart C--Establishment Inspection

§ 600.20 - Inspectors.
§ 600.21 - Time of inspection.
§ 600.22 - [Reserved]

Subpart D--Reporting of Adverse Experiences

§ 600.80 – Post marketing reporting of adverse experiences.
§ 600.81 - Distribution reports.
§ 600.82 - Notification of a permanent discontinuance or an interruption in manufacturing.
§ 600.90 - Waivers.

Part 820 Quality system regulation

ICH-International Council for Harmonization	
Founding Regulatory Members - Europe United States, Japan in 1990. ICH topics divided into 4 categories - Q S E M [Quality, Safety, Efficacy and Multi-disciplinary guidelines]	
Quality	
Q1A - Q1F Stability	
Q1A (R2)	Stability Testing of New Drug Substances and Products
Q1B	Stability Testing : Photo stability Testing of New Drug Substances and Products
Q1C	Stability Testing for New Dosage Forms
Q1D	Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
Q1E	Evaluation of Stability Data
Q1F	Stability Data Package for Registration Applications in Climatic Zones III and IV
Q2 Analytical Validation	
Q2(R1)	Validation of Analytical Procedures: Text and Methodology
Q2(R2)/Q14	EWG Analytical Procedure Development and Revision of Q2 (R1) Analytical Validation
Q3A-Q3E Impurities	
Q3A(R2)	Impurities in New Drug Substances
Q3B(R2)	Impurities in New Drug Products
Q3C(R6)	Maintenance of the Guideline for Residual Solvents
Q3C(R8)	Maintenance EWG Maintenance of the Guideline for Residual Solvents
Q3D(R1)	Guideline for Elemental Impurities
Q3D(R2)	Maintenance EWG Revision of Q3D (R1) for cutaneous and transdermal products
Q3D	Training Implementation of Guideline for Elemental Impurities
Q3E	EWG Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics
Q4A - Q4B Pharmacopoeias	
Q4A	Pharmacopoeial Harmonization
Q4B	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions
Q4B Annex 1(R1)	Residue on Ignition/Sulphated Ash General Chapter
Q4B Annex 2(R1)	Test for Extractable Volume of Parenteral Preparations General Chapter
Q4B Annex 3(R1)	Test for Particulate Contamination: Sub-Visible Particles General Chapter
Q4B Annex 4A(R1)	Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter
Q4B Annex 4A(R1)	Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter
Q4B Annex 4C(R1)	Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter
Q4B Annex 5(R1)	Disintegration Test General Chapter
Q4B Annex 6	Uniformity of Dosage Units General Chapter
Q4B Annex 7(R2)	Dissolution Test General Chapter
Q4B Annex 8(R1)	Sterility Test General Chapter
Q4B Annex 9(R1)	Tablet Friability General Chapter
Q4B Annex 10(R1)	Polyacrylamide Gel Electrophoresis General Chapter
Q4B Annex 11	Capillary Electrophoresis General Chapter
Q4B Annex 12	Analytical Sieving General Chapter
Q4B Annex 13	Bulk Density and Tapped Density of Powders General Chapter
Q4B Annex 14	Bacterial Endotoxins Test General Chapter
Q4B	FAQs Frequently Asked Question
Q5A - Q5E Quality of Biotechnological Products	
Q5A(R1)	Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
Q5A(R2)	EWG Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
Q5B	Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products
Q5C	Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products
Q5D	Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products
Q5E	Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process

Q6A- Q6B Specifications	
Q6A	Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances
Q6B	Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products
Q7 Good Manufacturing Practice	
Q7	Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
Q7	Q&A Questions and Answers: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
Q8 Pharmaceutical Development	
Q8(R2)	Pharmaceutical Development
Q8/9/10 Q&As (R4)	Q8/Q9/Q10 - Implementation
Q9 Quality Risk Management	
Q9	Quality Risk Management
Q9(R1)	EWG Quality Risk Management
Q8/9/10 Q&As (R4)	Q8/Q9/Q10 – Implementation
Q10 Pharmaceutical Quality System	
Q10	Pharmaceutical Quality System
Q8/9/10 Q&As (R4)	Q8/Q9/Q10 – Implementation
Q11 Development and Manufacture of Drug Substances	
Q11	Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)
Q11 Q&A	Questions & Answers: Selection and Justification of Starting Materials for the Manufacture of Drug Substances
Q12 Lifecycle Management	
Q12	Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
Q12	IWG Training on Regulatory and Technical Considerations for Pharmaceutical Product Lifecycle Management
Q13 Continuous Manufacturing of Drug Substances and Drug Products	
Q13	EWG Continuous Manufacturing of Drug Substances and Drug Products
Q14 Analytical Procedure Development	
Q2(R2)/Q14	EWG Analytical Procedure Development and Revision of Q2 (R1) Analytical Validation
Safety	
S1A - S1C Carcinogenicity Studies	
S1A	Need for Carcinogenicity Studies of Pharmaceuticals
S1B	Testing for Carcinogenicity of Pharmaceuticals
S1C(R2)	Dose Selection for Carcinogenicity Studies of Pharmaceuticals
S1(R1)	EWG Rodent Carcinogenicity Studies for Human Pharmaceuticals
S2 Genotoxicity Studies	
S2(R1)	Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use
S3A - S3B Toxico kinetics and Pharmacokinetics	
S3A	Note for Guidance on Toxico kinetics: The Assessment of Systemic Exposure in Toxicity Studies
S3A Q&As	Questions and Answers: Note for Guidance on Toxico kinetics: The Assessment of Systemic Exposure - Focus on Micro sampling
S3B	Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies
S4 Toxicity Testing	
S4	Duration of Chronic Toxicity Testing in Animals (Rodent and Non Rodent Toxicity Testing)
S5 Reproductive Toxicology	
S5(R3)	Revision of S5 Guideline on Detection of Toxicity to Reproduction for Human Pharmaceuticals
S5(R4)	Maintenance EWG Revision of S5 Guideline on Detection of Toxicity to Reproduction for Human Pharmaceuticals
S6 Biotechnological Products	
S6(R1)	Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals
S7A - S7B Pharmacology Studies	
S7A	Safety Pharmacology Studies for Human Pharmaceuticals
S7B	The Non-Clinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals
E14/S7B	IWG Questions & Answers: Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential

S8 Immunotoxicology Studies	
S8	Immunotoxicity Studies for Human Pharmaceuticals
S9 Nonclinical Evaluation for Anticancer Pharmaceuticals	
S9	Nonclinical Evaluation for Anticancer Pharmaceuticals
S9 Q&As	Questions and Answers: Nonclinical Evaluation for Anticancer Pharmaceuticals
S10 Photo safety Evaluation	
S10	Photosafety Evaluation of Pharmaceuticals
S11 Nonclinical Paediatric Safety	
S11	Nonclinical Safety Testing in Support of Development of Paediatric Medicines
S12 Non-clinical Bio distribution Studies for Gene Therapy Products	
S12	EWG Non-clinical Bio distribution Studies for Gene Therapy Products
Efficacy	
E1 Clinical Safety for Drugs used in Long-Term Treatment	
E1	The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life Threatening Conditions
E2A - E2F Pharmacovigilance	
E2A	Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
E2B (R3)	Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (ICSRs)
E2B (R3)	Q&As Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
E2B(R3)	EWG/IWG Electronic Transmission of Individual Case Safety Reports (ICSRs)
E2C(R2)	Periodic Benefit-Risk Evaluation Report
E2C(R2)	Q&As Questions & Answers: Periodic Benefit-Risk Evaluation Report
E2D	Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting
E2D(R1)	EWG Post Approval Safety Data Management: Definition and Standards for Expedited Reporting
E2E	Pharmacovigilance Planning
E2F	Development Safety Update Report
E3 Clinical Study Reports	
E3	Structure and Content of Clinical Study Reports
E3 Q&As (R1)	Questions & Answers: Structure and Content of Clinical Study Reports
E4 Dose-Response Studies	
E4	Dose-Response Information to Support Drug Registration
E5 Ethnic Factors	
E5(R1)	Ethnic Factors in the Acceptability of Foreign Clinical Data
E5 Q&As (R1)	Questions & Answers: Ethnic Factors in the Acceptability of Foreign Clinical Data
E6 Good Clinical Practice	
E6(R2)	Good Clinical Practice (GCP)
E6(R3)	EWG Good Clinical Practice (GCP)
E7 Clinical Trials in Geriatric Population	
E7	Studies in Support of Special Populations: Geriatrics
E7 Q&As	Questions & Answers: Studies in Support of Special Populations: Geriatrics
E8 General Considerations for Clinical Trials	
E8	General Considerations for Clinical Trials
E8(R1)	EWG Revision on General Considerations for Clinical Studies
E9 Statistical Principles for Clinical Trials	
E9	Statistical Principles for Clinical Trials
E9(R1)	EWG Addendum: Statistical Principles for Clinical Trials
E10 Choice of Control Group in Clinical Trials	
E10	Choice of Control Group and Related Issues in Clinical Trials
E11 - E11A Clinical Trials in Pediatric Population	
E11 (R1)	Addendum: Clinical Investigation of Medicinal Products in the Pediatric Population

E11A	EWG Paediatric Extrapolation
E12 Clinical Evaluation by Therapeutic Category	
E12	Principles for Clinical Evaluation of New Antihypertensive Drugs
E14 Clinical Evaluation of QT	
E14	The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
E14 Q&As (R3)	Questions & Answers: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
E14/S7B	IWG Questions & Answers: Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential
E15 Definitions in Pharmacogenetics / Pharmacogenomics	
E15	Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories
E16 Qualification of Genomic Biomarkers	
E16	Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure and Format of Qualification Submissions
E17 Multi-Regional Clinical Trials	
E17	General principles for planning and design of Multi-Regional Clinical Trials
E18 Genomic Sampling	
E18	Genomic Sampling and Management of Genomic Data
E19 Safety Data Collection	
E19	EWG Optimization of Safety Data Collection
E20 Adaptive Clinical Trials	
E20	EWG Adaptive Clinical Trials
	Multidisciplinary Guidelines
M1 Med DRA Terminology	
M1	Med DRA - Medical Dictionary for Regulatory Activities
M1 PtC WG	Med DRA Points to Consider
M2 Electronic Standards	
M2 EWG	Electronic Standards for the Transfer of Regulatory Information
M3 Nonclinical Safety Studies	
M3(R2)	Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals
M3(R2) Q&As	(R2)Questions & Answers: Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals
M4 Common Technical Document	
CTD	The Common Technical Document
M5 Data Elements and Standards for Drug Dictionaries	
M5	Data Elements and Standards for Drug Dictionaries
M6 Gene Therapy	
M6	Virus and Gene Therapy Vector Shedding and Transmission
M7 Mutagenic impurities	
M7(R1)	Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk
M7(R2)	Maintenance EWG/IWG Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk
M8 Electronic Common Technical Document (eCTD)	
M8 eCTD v3.2.2	Electronic Common Technical Document (eCTD) v3.2.2
M8 eCTD v4.0	Electronic Common Technical Document (eCTD) v4.0
M8 EWG/IWG	Electronic Common Technical Document (eCTD)
M9 Biopharmaceutics Classification System-based Biowaivers	
M9	Biopharmaceutics Classification System-based Biowaivers
M9 Q&As	Q&As on Biopharmaceutics Classification System-based Biowaivers
M10 Bioanalytical Method Validation	
M10 EWG	Bioanalytical Method Validation
M11 Clinical electronic Structured Harmonized Protocol (CeSHarP)	
M11 EWG	Clinical electronic Structured Harmonized Protocol (CeSHarP)

M12 Drug Interaction Studies	
M12 EWG	Drug Interaction Studies
M13 Bioequivalence for Immediate-Release Solid Oral Dosage Forms	
M13 EWG	Bioequivalence for Immediate-Release Solid Oral Dosage Forms

ISO 14644 Standards First formed from the US Federal Standard 209E Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones. The first document of ISO 14644-1 was published in 1999. In 2000, ISO 14644-2 was published, which began the process of FED-STD-209E being canceled. On November 29, 2001, the document was canceled and superseded by ISO 14644-1 and ISO 14644-2.		
ISO 14644-1	Classification of air cleanliness by particle concentration	Covers the classification of air cleanliness in cleanrooms and associated controlled environments.
ISO 14644-2	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Specifies requirements for monitoring and periodic testing of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1.
ISO/ANS 14644-3	Test methods	Specifies test methods for designated classification of airborne particulate cleanliness for characterizing the performance of cleanrooms and clean zones.
ISO 14644-3	Test methods	This ISO Standard has not been approved as an American National Standard, and does not replace ANSI/IEST/ISO 14644-3:2005.
ISO 14644-4	Design, construction, and start-up	Specifies requirements for the design and construction of cleanroom installations.
ISO 14644-5	Operations	Specifies basic requirements for cleanroom operations.
ISO 14644-6	Vocabulary	Vocabulary
ISO 14644-7	Separative devices (clean air hoods, gloveboxes, isolators, minienvironments)	Specifies the minimum requirements for the design, construction, installation, testing and approval of separative devices.
ISO 14644-8	Classification of air cleanliness by chemical concentration (ACC)	Covers the classification of airborne molecular contamination (AMC) in cleanrooms and associated controlled environments.
ISO 14644-9	Classification of surface particle cleanliness	Establishes the classification of cleanliness levels on solid surfaces by particle concentration in cleanrooms and associated controlled environments.
ISO 14644-10	Classification of surface cleanliness by chemical concentrations	Defines the classification system for cleanliness of surfaces in cleanrooms with regard to the presence of chemical compounds or elements.
ISO 14644-12	Specifications for monitoring air cleanliness by nanoscale particle concentration	Covers the monitoring of air cleanliness by particles in terms of concentration of airborne nanoscale particles.
ISO 14644-13	Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications	Addresses the cleaning to a specified degree on cleanroom surfaces, surfaces of equipment in a cleanroom and surfaces of materials in a cleanroom.
ISO 14644-14	Assessment of suitability for use of equipment by airborne particle concentration	Specifies a methodology to assess the suitability of equipment for use in cleanrooms and associated controlled environments.
ISO 14644-15	Assessment of suitability for use of equipment and materials by airborne chemical concentration	Provides requirements and guidance for assessing the chemical airborne cleanliness of equipment and materials, which are foreseen to be used in cleanrooms and associated controlled environments.
ISO 14644-16	Code of practice for improving energy efficiency in cleanrooms and clean air devices	Provides guidance and recommendations for optimizing energy usage and maintaining energy efficiency in new and existing cleanrooms, clean zones and separative devices.
ISO/FDIS 14644-17	Particle deposition rate applications	Provides guidance on the interpretation and application of the results of the measurement of Particle Deposition Rate (PDR) on one, or more vulnerable surfaces in a cleanroom as part of a contamination control program.

PIC/S - Pharmaceutical Inspection Co-operation Scheme

Is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any Authority having a comparable GMP inspection system. PIC countries-Austria, Denmark, Finland, Iceland, Liechtenstein, Norway, Portugal, Sweden, Switzerland and United Kingdom. Membership of PIC was subsequently expanded to include Hungary, Ireland, Romania, Germany, Italy, Belgium, France and Australia. Leading the international development, implementation and maintenance of harmonized GMP standards and quality systems of Inspectorates in the field of medicinal products.

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was established in 1995 as an extension to the Pharmaceutical Inspection Convention (PIC) of 1970 by EFTA (European Free Trade Association) under the title of “The Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products. PIC/S aims at harmonizing inspection procedures worldwide by developing common standards in the field of GMP and by providing training opportunities to Inspectors. It also aims at facilitating co-operation and networking between competent authorities, regional and international organizations, thus increasing mutual confidence.

It was realized in the early 1990s that because of an incompatibility between the Convention and European law, it was not possible for new countries to be admitted as Members of PIC. Australia was the last country that was able to become a Member of PIC in January 1993. PIC and the PIC Scheme, which operate together in parallel, are jointly referred to as PIC/S.
The original goals of PIC were:

- Mutual recognition of inspections;
- Harmonization of GMP requirements;
- Uniform inspection systems;
- Training of Inspectors;
- Exchange of information;
- Mutual confidence.

In 1989, the EU adopted its own GMP Guide, which - in terms of GMP requirements - is equivalent to the PIC/S GMP Guide. Since that time, the EU and the PIC/S GMP Guides have been developed in parallel [both Guides are practically identical].

In addition to the GMP Guide, PIC/S has also been a pioneer in developing a number of guidelines and guidance documents such as the Site Master File, the Recommendation on Quality System Requirements for Pharmaceutical Inspectorates and the first Guideline for the Manufacture of Active Pharmaceutical Ingredients.

GMP guide

PE 009-14	PIC/S GMP guide [Introduction]
PE 009-14 [Part I]	PIC/S GMP guide [Part I-Basic requirements for medicinal products]
PE 009-14 [Part II]	PIC/S GMP guide [Part II-Basic requirements for API]
PE 009-14 [Annexes]	PIC/S GMP guide [Related Annexes]

PDA Parenteral Drug Association	
Is an international non-profit industry trade group for pharmaceutical and biopharmaceutical manufacturers headquartered in Bethesda, MD, USA, with offices in Berlin, Germany, and Singapore. The Parenteral Drug Association (PDA) is the leading global provider of science, technology, regulatory information, and education for the bio/pharmaceutical community. For nearly 75 years, since its founding as a non-profit in 1946, PDA has been committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of our more than 10,500 members worldwide. PDA supports its mission to advance pharmaceutical and biopharmaceutical science and regulation so members can better serve patients by: • Providing global forums for the scientific community, regulators, and industry professionals on emerging trends within the industry • Delivering unique, hands-on education and training courses through PDA's manufacturing training facility • Fostering career-long learning and professional development • Encouraging scientific information sharing among industry peers • Serving as a leading contributor of information and expertise to influence global industry and regulatory solutions.	
PDA Technical reports	
01	Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control
02	Validation of Dry Heat Processes Used for Depyrogenation and Sterilization
03	Design Concepts for the Validation of a Water for Injection System (Retired)
04	Sterile Pharmaceutical Packaging: Compatibility and Stability (Retired)
05	Depyrogenation (Retired)
06	Review of Commercially Available Particulate Measurement Systems (Retired)
07	Parenteral Formulations of Proteins and Peptides: Stability and Stabilizers (Retired)
08	Sterilization of Parenterals by Gamma Radiation (Retired)
09	Siliconization of Parenteral Drug Packaging Components
10	Fundamentals of an Environmental Monitoring Program
11	Validation of Column-Based Chromatography Processes for the Purification of Proteins
12	Validation of Tangential Flow Filtration in Biopharmaceutical Applications
13	Effects of Gamma Irradiation on Elastomeric Closures (Retired)
14	Current Practices in the Validation of Aseptic Processing -- 1992 (Retired)
15	Validation of Computer-Related Systems (Retired)
16	Rapid/Automated ID Methods Survey (Retired)
17	Report on Survey of Current Industry Gowning Practices (Retired)
18	Bioburden Recovery Validation (Retired)
19	Process Simulation for Aseptically Filled Products
20	Industry Survey on Current Sterile Filtration Practices (Retired)
21	Current Practices in the Validation of Aseptic Processing (Retired)
22	Blend Uniformity Analysis: Validation and In-Process Testing (Retired)
23	Sterilizing Filtration of Liquids
24	Pharmaceutical Package Integrity
25	Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals
26	Points to Consider for Cleaning Validation
27	Parametric Release of Pharmaceuticals and Medical Device Products Terminally Sterilized by Moist heat
28	Validation and Qualification of Computerized Laboratory Data Acquisition Systems (Retired)
29	Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations (Retired)
30	Evaluation, Validation and Implementation of Alternative and Rapid Microbiological methods
31	Design and Validation of Isolator Systems for the Manufacturing and Testing of health care products
32	A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry (Retired)
33	Current Practices in the Validation of Aseptic Processing – 2001 (Retired)
34	Manufacturing Chromatography Systems Post approval Changes (ChromPAC): Chemistry, Manufacturing, and Controls Documentation
35	Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment
36	Sterilization Filtration of Gases
37	Virus Filtration
38	Process Validation of Protein Manufacturing
39	Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing: Covering Ampoules, Bottles, Cartridges, Syringes and Vials
40	Quality Risk Management for Aseptic Processes
41	Filtration of Liquids Using Cellulose-Based Depth Filters
42	Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End User
43	Preparation of Virus Spikes Used for Virus Clearance Studies

44	Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance
45	Points to Consider for Biotechnology Cleaning Validation
46	Alternative Methods for Mycoplasma Testing
47	Biological Indicators for Gas and Vapor-Phase Decontamination Processes: Specification, Manufacture, Control and Use
48	Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain
49	Guidance for Industry: Stability Testing to Support Distribution of New Drug Products
50	Implementation of Quality Risk Management For Pharmaceutical and Biotechnology Manufacturing Operations
51	Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations Annex 1: Case Study Examples for Quality Risk Management in Packaging and Labeling
52	Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations Annex 2: Case Studies in the Manufacturing of Pharmaceutical Drug Products
53	Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations Annex 3: Case Studies in the Manufacturing of Biotechnological Bulk Drug Substances
54	Detection and Mitigation of 2,4,6-Tribromoanisole and 2,4,6-Trichloroanisole Taints and Odors in the Pharmaceutical and Consumer Healthcare Industries
55	Application of Phase-Appropriate Quality System and cGMP to the Development of Therapeutic Protein Drug Substance (API or Biological Active Substance)
56	Analytical Method Validation and Transfer for Biotechnology Products
57	Analytical Method Development and Qualification for Biotechnology Products
58	Risk Management for Temperature-Controlled Distribution
59	Utilization of Statistical Methods for Production Monitoring
60	Process Validation: A Lifecycle Approach
61	Process Validation: A Lifecycle Approach Annex 1: Oral Solid Dosage/Semisolid dosage forms
62	Steam In Place
63	Recommended Practices for Manual Aseptic Processes
64	Quality Requirements for the Extemporaneous Preparation of Clinical Trial Materials
65	Active Temperature-Controlled Systems: Qualification Guidance
66	Technology Transfer
67	Application of Single-Use Systems in Pharmaceutical Manufacturing
68	Exclusion of Objectionable Microorganisms from Nonsterile Pharmaceuticals, Medical Devices, and Cosmetics
69	Risk-Based Approach for Prevention and Management of Drug Shortages
70	Bioburden and Biofilm Management in Pharmaceutical Manufacturing Operations
71	Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities
72	Emerging Methods for Virus Detection
73	Passive Thermal Protection Systems for Global Distribution: Qualification and Operational Guidance
74	Prefilled Syringe User Requirements for Biotechnology Applications
75	Reprocessing of Biopharmaceuticals
76	Consensus Method for Rating 0.1µm Mycoplasma Reduction Filters
77	Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging
78	The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology
79	Quality Risk Management for the Design, Qualification, and Operation of Manufacturing Systems
80	Particulate Matter in Oral Dosage Forms
81	Particulate Matter Control in Difficult to Inspect Parenterals
82	Data Integrity Management System for Pharmaceutical Laboratories
83	Cell-Based Therapy Control Strategy
84	Low Endotoxin Recovery
85	Virus Contamination in Bio manufacturing: Risk Mitigation, Preparedness, and Response
86	Formalized Risk Assessment for Excipients
87	Integrating Data Integrity Requirements into Manufacturing & Packing Operations

ISPE-International Society for Pharmaceutical Engineering
The International Society for Pharmaceutical Engineering is the world's largest not-for-profit association serving its members by leading scientific, technical and regulatory advancement throughout the entire pharmaceutical lifecycle. ISPE was founded in 1980 by a handful of people who believed the pharmaceutical industry needed an organization that would deal with practical applications of science and technology for technical professionals. The much-needed forum provided by ISPE began with a Membership of engineers in North America. In time, ISPE Membership expanded beyond engineering to include a broad representation from pharmaceutical professionals.
GAMP GAMP 5 Guide: Compliant GxP Computerized Systems GAMP Guide: Records & Data Integrity GAMP Good Practice Guides GAMP Good Practice Guide: Calibration Management 2nd Edition GAMP Good Practice Guide: Computerized GCP Systems & Data GAMP Good Practice Guide: Global Info Systems Control & Compliance 2nd Edition GAMP Good Practice Guide: GxP Compliant Laboratory Computerized Systems 2nd Edition GAMP Good Practice Guide: GxP Process Control Systems 2nd Edition GAMP Good Practice Guide: IT Infrastructure Control and Compliance 2nd Edition GAMP Good Practice Guide: Manufacturing Execution Systems GAMP Good Practice Guide: Operation of GxP Computerized Systems GAMP Good Practice Guide: Regulated Mobile Applications GAMP Good Practice Guide: Testing GxP Systems 2nd Edition GAMP RDI Good Practice Guide: Data Integrity - Key Concepts GAMP RDI Good Practice Guide: Data Integrity - Manufacturing Records GAMP RDI Good Practice Guide: Data Integrity by Design Good Practice Guides Good Practice Guide: Assessing Particulate Containment 2nd Edition Good Practice Guide: Asset Management Good Practice Guide: Booklet Labels Good Practice Guide: C&Q of Pharma Water & Steam Systems 2nd Edition Good Practice Guide: Clinical Supply Systems Good Practice Guide: Cold Chain Management Good Practice Guide: Comparator Management Good Practice Guide: Controlled Temperature Chamber Mapping & Monitoring Good Practice Guide: Critical Utilities GMP Compliance Good Practice Guide: Decommissioning Pharma Equipment & Facilities Good Practice Guide: Development of Investigational Therapeutic Biological Products Good Practice Guide: Good Engineering Practice Good Practice Guide: Harmonizing the Definition and Use of NIMPs Good Practice Guide: Heating, Ventilation, & Air Conditioning (HVAC) Good Practice Guide: HVAC & Process Equipment Air Filters Good Practice Guide: Interactive Response Technology Good Practice Guide: Maintenance Good Practice Guide: Management of Engineering Standards Good Practice Guide: Operations Management Good Practice Guide: Ozone Sanitization of Pharma Water Systems Good Practice Guide: Packaging, Labeling, & Warehousing Facilities Good Practice Guide: Process Gases Good Practice Guide: Process Validation Good Practice Guide: Project Management for Pharmaceutical Industry Good Practice Guide: Quality Lab Facilities Good Practice Guide: Sampling Pharma Water, Steam, & Process Gases Good Practice Guide: Single-Use Technology Good Practice Guide: Technology Transfer 3rd Edition Baseline Guides Baseline Guide Vol 1: Active Pharmaceutical Ingredients Baseline Guide Vol 2: Oral Solid Dosage Forms 3rd Edition Baseline Guide Vol 3: Sterile Product Manufacturing Facilities 3rd Edition

Baseline Guide Vol 4: Water & Steam Systems 3rd Edition
Baseline Guide Vol 5: Commissioning & Qualification 2nd Edition
Baseline Guide Vol 6: Biopharmaceutical Manufacturing Facilities 2nd Edition
Baseline Guide Vol 7: Risk-Based Manufacture of Pharma Products 2nd Edition

PQLI

Product Quality Implementation Lifecycle (PQLI) Guides provide information on global solutions to implementation challenges of International Council for Harmonization (ICH) guidances.

PQLI Guide: Part 1 - Product Realization using QbD: Concepts & Principles
PQLI Guide: Part 2 - Product Realization using QbD: Illustrative Example
PQLI Guide: Part 3 - Change Management System
PQLI Guide: Part 4 - Process Performance & Product Quality Monitoring System

Guide

Guide: Biopharmaceutical Process Development & Manufacturing
Guide: Cleaning Validation Lifecycle - Applications, Methods, & Controls

TGA-Therapeutic Goods Administration [Australia]
Almost any product with therapeutic claims are made must be entered in the Australian register of Therapeutic goods [ARTG] before it can be supplied in Australia
The current Therapeutic Goods (Manufacturing Principles) specifies that medicinal products supplied in Australia have to meet the PIC/S Guide to Good Manufacturing Practice (GMP) - 01 July 2018, PE009-14, except for its Annexes 4, 5 and 14 which are not adopted by Australia

MCC-Medicines Control Council [South Africa]
As a participating authority of PIC/S, the MCC requires that manufacturers, importers and exporters of medicines and related substances in South Africa meet the standards laid out in the PIC/S Guide to Good Manufacturing Practice (GMP). As such, the MCC has adopted the PIC/S Guide to GMP and all prospective adaptations as prescribed by the PIC/S.
SA guide to GMP for medicines-Version 6 Dec 2017.

MHRA-Medicines and healthcare products regulatory agency [United Kingdom]
The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK.

EMA - European Medicines Agency [European union]
The (EMA) is an agency of the European Union (EU) in charge of the evaluation and supervision of medicinal products. Prior to 2004, it was known as the European Agency for the Evaluation of Medicinal Products or European Medicines Evaluation Agency [EMEA]

USFDA - United States Food and Drug Administration [United states]
The United States Food and Drug Administration (FDA or USFDA) is a federal agency of the Department of Health and Human Services

Medical Device Single Audit Program [MDSAP]
Therapeutic Goods Administration of Australia Brazil's Agência Nacional de Vigilância Sanitária Health Canada Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency U.S. Food and Drug Administration

ISO 13485
Is an International Organization for Standardization [ISO] standard published for the first time in 1996; it represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices. This standard supersedes earlier documents such as EN 46001 (1993 and 1996) and EN 46002 (1996), the previously published ISO 13485 (1996 and 2003), and ISO 13488 [also 1996].