

The 7 Technical Knowledge Elements of the CPIP Credential

Knowledge Element 1 - Product Development

Overview: Through the interactions of multi-disciplinary functions and the scientific application of experimental design methodologies, implement a process to reproducibly and economically manufacture a product of (a) the desired formulation, dosage form, and specifications that meets predicted quality; (b) is optimized for purity, potency, and efficacy; and (c) facilitates continuous improvement.

Formulation, Clinical Phases, and Manufacture

1. Knowledge of functions and pathways involved in product development
2. Knowledge of the purpose and conduct of clinical trials Phases I, II, and III
3. Knowledge of the impact of decisions (for example, dosage forms, batch size, production method, outsourcing) during drug development on product lifecycle viability and success
4. Knowledge of the production process and the role of interactions of ingredients/materials employed in pharmaceutical development and manufacturing
5. Knowledge of the impact of the processing, storage, and transport environments on ingredients/materials and semi- and finished goods
6. Knowledge of the impact of methods of measurement and control on product and process quality and stability
7. Knowledge that the physical and chemical attributes of the product have implications in production

Technology Transfer

8. Knowledge of the critical activities and success factors required for an effective and efficient technology transfer
9. Knowledge of requirements for planning, execution, and assimilation of technology and knowledge transfer

Production Scale-Up and Optimization

10. Knowledge of the options to increase and/or optimize production
11. Knowledge of the critical factors (for example, rate change, mechanistic properties, equipment design) of scale-up and their impact on manufacturability
12. Knowledge of the impact of factors that can positively or negatively affect scale-up
13. Knowledge of modeling techniques for optimization of product cycle time

Knowledge Element 2 - Facilities and Equipment

Overview: Knowledge required to ensure: (a) that the critical physical and chemical requirements of drug products are properly understood and managed; and (b) that the selection of process equipment and the design of facilities and support utility systems will consistently deliver those requirements and all other aspects of the product specification (including quantity and timely delivery)

Design and Construction/Installation

1. Knowledge of requirements for product protection and containment
2. Knowledge of requirements for personnel and environmental safety and protection
3. Knowledge of the importance of personnel flow and materials flow and their implications for layout
4. Knowledge of the materials and methods of construction of equipment and facilities, particularly from the perspective of cleanliness, functionality, and maintainability
5. Knowledge of critical process equipment and utility systems' attributes (performance, functionality, construction, instrumentation) and their impact on personnel and product
6. Knowledge of cleaning systems including CIP/SIP
7. Knowledge of the fundamentals of good engineering practice

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Commissioning and Qualification as a Risk Management Strategy

8. Knowledge of factors that can impact the commissioning and qualification process
9. Knowledge of requirements for executing and documenting the commissioning and qualification
10. Knowledge of concepts, sequencing, and documentation of commissioning and qualification activities required by design intent
11. Knowledge of critical systems impact assessment and implications for the product

Operation and Maintenance

12. Knowledge of equipment and facility reliability and predictability models to establish a maintenance and calibration program
13. Knowledge of equipment operability and maintenance (location and access, type, and frequency of maintenance)
14. Knowledge of linkage of product and process development to operation and maintenance of process equipment and facilities
15. Knowledge of continuous operations improvement

Controls and Automation

16. Knowledge of building management systems
17. Knowledge of types of process automation and associated controls

Knowledge Element 3 - Information Systems

Overview: Knowledge of (a) the types of information and data management systems that are integral to successful drug development, manufacturing, and distribution; and (b) the controls and methods necessary to maintain data integrity and security.

1. Knowledge of data management systems with product and financial impact (for example, manufacturing execution systems [MES], laboratory information management systems [LIMS], electronic document management systems [EDMS], and enterprise resource planning)
2. Knowledge of the basic computer system life cycle model and the activities and software quality assurance practices in each phase
3. Knowledge of data integrity and security measures, such as back-up, archiving, and retention requirements

Knowledge Element 4 - Supply Chain Management

Overview: Knowledge of (a) the key components of the supply and distribution chains and their financial impact; (b) the systems required for dynamically controlling and automating receipt, storage and dispensing of raw materials and packaging materials; and (c) storage and distribution of finished products, so that the integrity of the product is not impaired by any of these processes.

Materials Management

1. Knowledge of the key components of the supply chain
2. Knowledge of supply chain and inventory models (for example, Kanban, JIT, APICS)
3. Knowledge of supply chain constraints that impact material and product throughput and their mitigation strategies
4. Knowledge of contributors to market projections and supply chain strategy for product

Operational Economics

5. Knowledge of the controls required for purchasing, receipt, storage, and dispensing of raw materials, and packaging materials and their related impacts on costs
6. Knowledge of industrial engineering standards and application to capital investments, facility and equipment utilization, and operational efficiencies

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Warehouse and Distribution Management

7. Knowledge of warehouse and distribution management systems
8. Knowledge of transportation and logistic systems
9. Knowledge of environmental storage and transportation controls for hazardous and non-hazardous materials
10. Knowledge of distribution chain security and product disposition controls

Knowledge Element 5 - Production Systems

Overview: Knowledge of (a) the full range and scope of unit operations and production steps for manufacturing APIs and both small molecule and biologic pharmaceuticals; (b) the building and critical process utility systems that support the manufacturing process; and (c) the means of managing and dynamically controlling and automating manufacturing and warehousing operations.

Production Unit Operations - Drug (small molecule) and Biologics

1. Knowledge of manufacture of active pharmaceutical ingredients, components, and excipients
2. Knowledge of unit operations
3. Knowledge of labeling and packaging operations
4. Knowledge of critical process equipment and utility systems' attributes (performance, functionality, construction, instrumentation) and their impact on personnel and product
5. Knowledge of the controls required for receipt, storage, and dispensing of raw materials, and packaging materials
6. Knowledge of industrial engineering standards, facility and equipment utilization, and operational efficiencies

Production Management

7. Knowledge of production management
8. Knowledge of storage requirements, production logistics, and RFID
9. Knowledge of environmental conditions, security, and status requirements

Production Control

10. Knowledge of batch records
11. Knowledge of contamination controls (for example, cleaning, segregation, HVAC) and changeover
12. Knowledge of critical factors that impact quality and how to control
13. Knowledge of methods and tools for data manipulation and analysis
14. Knowledge of critical quality attributes and process controls

Knowledge Element 6 - Regulatory Compliance

(includes drugs, environmental, health and safety)

Overview: A fundamental understanding of (a) international regulations and guidance issued by regulatory bodies and coalitions which shape the world's current pharmaceutical-related requirements and future directions, and (b) the application of regulations and industry-generated guidance for global harmonization of compliance and product registration.

Government Regulations

1. Knowledge of the role of regulatory bodies worldwide and their structure and operations
2. Knowledge of the role of legislation, regulations, guidance, and MRAs worldwide (for example, types of regulatory filings, GMPs)
3. Knowledge of the use of global compendia

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4. Knowledge of the common base in requirements of regulating bodies around the world and awareness that differences exist

Standards, Practices, and Guides

5. Knowledge of the role of industry-generated guidance relating to international harmonization (ICH guidance documents; ISPE Baseline[®] Guides, GAMP[®], and Good Practice Guides; and the PDA technical reports)
6. Knowledge of the role of common environment, health, and safety standards
7. Knowledge of the role of consensus standards (ISO, ANSI, ASTM)

Knowledge Element 7 - Quality Systems

Overview: Knowledge of the role and elements of a quality management system and its impact within the overall risk management approach, as well as its implementation in a scientific and pragmatic manner.

Risk Management and Quality Management System (QMS)

1. Knowledge of purpose, elements and implementation of a QMS
2. Knowledge of risk management strategies
3. Knowledge of purpose, elements and implementation of change control programs
4. Knowledge of purpose, elements and implementation of CAPA programs
5. Knowledge of the elements of an internal assessment program

Systems Validation (changed from Validated Controls)

6. Knowledge of purpose, elements and implementation of product, process, facility, equipment, computer system, analytical method, and contamination control programs
7. Knowledge of impact of emerging process development and control strategies on traditional validation practices