

# **ISPE Professional Certification Commission®**



## Item Writing Manual For CPIP<sup>SM</sup> Examination

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## I. Introduction

Dear Colleague,

On behalf of my fellow commissioners allow me to extend to you our sincere thanks for your commitment to participate as a Subject Matter Expert in our examination development efforts.

Over the last 18 months the commission and ISPE staff have been involved in the definition of a professional whose knowledge and personal convictions will set the direction for innovation in the pharmaceutical industry. This individual will possess the broad based knowledge and awareness to earn the Certified Pharmaceutical Industrial Professional (CPIP<sup>SM</sup>) credential. The scope and basis of this knowledge has been researched and validated during our exhaustive international practice analysis phase these past months.

In simple terms the international practice analysis was the validation of the envisioned knowledge elements and personal profile, gathered by questioning and surveying our fellow professionals working within our industry. Sixty Subject Matter Experts were presented with the definition of our credential along with the key aspects of knowledge and personal behavior we have established. Their response was the validation needed to move this credential into the next phase, which is the assessment, or examination development in which you will be a key contributor.

Each of you commands an expertise in a selected knowledge area. We now need to synthesize this knowledge and expertise into a battery of questions, which will explore the level of our candidate's knowledge. This is a unique task as we need to determine the candidate's "working" knowledge and yet strike a balance between the broad scope we expect from our candidates with the detailed knowledge, which you possess.

The use of broad strokes in crafting these questions, while not evaluating the candidates as Subject Matter Experts themselves, will call upon your talent and your ability to measure their understanding in all the seven knowledge elements. The broad scope of this credential must be rigorously tested and yet leave the detailed granularity reserved for true experts aside. This means you must reach into your own fundamental knowledge as a Subject Matter Expert and ask yourself, "What are the absolute essentials a well-rounded seasoned professional would need to know to practice their profession in our industry?"

Development of examination content aimed at evaluating a candidate's ability and yet not cross the line between true subject matter mastery and subject matter generalist will be a difficult task and one which we are confident you will deliver to all our satisfaction.

In your efforts we would ask that source documents or better stated the standard references you as a Subject Matter Expert would access also be listed. This will provide the study guidance our candidates will need to properly prepare for the examination. Ask yourself the question if I was limited to one or two key sources what would they be?

Thank you for your unselfish commitment and personal conviction as a thought leader to the help launch this industry guiding credential, good luck.

Sincerely,



Russ Somma, Ph. D.  
Chairman  
ISPE Professional Certification Commission

The CPIP examination is a computer-based test (CBT) composed of 150 multiple choice questions (items). Each item will have four options for the examinee to choose from. There is only one correct answer for each question.

The knowledge to be tested is identified in section four of this manual. Each Subject matter expert (SME) is assigned specific knowledge-of statements (KOSs) within the knowledge elements. Carefully read the knowledge element overview as well as the knowledge-of statements assigned to you. The items are to be written to test the candidates recall or understanding of the knowledge topics.

This item writing manual is to be used as a guide by the SME item writers. Each SME will be required to attend an interactive item writing workshop, via webinar, where good and poor example items will be written, reviewed, and discussed.

## II. CPIP Background

The CPIP credential was developed to serve the pharmaceutical and biotechnology industries by establishing a global standard for professionals involved in the development and manufacture of drug products. The award of the CPIP credential signifies recognition of “change agents” capable of fostering innovation and quality enhancements for the pharmaceutical and biotechnology industries.

### Functional Description:

The CPIP has broad industry knowledge and experience and applies the following competencies to achieve cost-effective, risk-based approaches, innovation, quality by design, and continuous improvement.

1. Technical knowledge
2. Leadership and professionalism
3. Integration/innovation/change advocacy
4. Quality and continuous improvement focus

The technical knowledge competency includes the following knowledge elements.

1. Product development
2. Facilities and equipment
3. Information systems
4. Supply chain management
5. Production systems
6. Regulatory compliance (includes drugs, environmental, health and safety)
7. Quality systems

### III. Item Writing Guidelines

The CPIP computer-based test item contains three components: *stem*, *response options*, and *correct response (key)*. The response options are arranged in a *sequence (seq)*. Only one response BEST answers or completes the stem.

Example A: (open stem – choices complete the statement)

**Stem** The traceability matrix should be designed to\_\_\_:

**Key** **Seq** **Response options**

- |   |   |   |
|---|---|---|
| Y | A | minimize duplication of testing.                          |
|   | B | aid in the planning of the validation schedule.           |
|   | C | be included and approved in the validation master plan.   |
|   | D | provide a framework for the planning of design documents. |

Example B: (closed stem – asks a question and ends with a question mark)

**Stem** Most firms express inventory turnover by using which of the following calculations?

**Key** **Seq** **Response options**

- |   |   |   |
|---|---|---|
| Y | A | Cost of goods sold during a time period divided by average inventory value during the time period |
|   | B | Units sold during a time period divided by average units in inventory during the time period      |
|   | C | Sales revenue during a time period divided by average inventory value at selling price            |
|   | D | Cost of goods sold during a time period divided by sales revenue during the time period           |

In multiple choice tests, the examinee is required to choose the BEST response from the four response options. The correct response must be unquestionably correct. Distractors (i.e., plausible but incorrect answers) must be developed for the remaining response options.

EVERY ITEM MUST HAVE A VIABLE PUBLISHED REFERENCE, FOUND IN THE PUBLIC DOMAIN, IDENTIFIED TO SUPPORT THE CORRECT ANSWER.

Meeting the goal of high quality test items requires adherence to some guidelines. You may refer to the following guidelines for creating the stem and response options and identifying references.

First identify concepts and ideas that relate to the specific knowledge element and KOS assigned. If the item does not relate to the KOS it cannot be considered for the examination. Draw upon your work experiences to create unique items. Make the items “user friendly”. Can you understand and answer the item?

### Writing the stem

Stems should:

- Provide sufficient information
- Avoid extra information
- Be grammatically correct
- Avoid clues that help give away answers
- Avoid negatives and absolutes
- Avoid second person

- 1) The stem should be written so the examinee knows what the focus of the item is. Item stems should always contain the main idea. The examinee should always know what is being asked in the item after reading the stem.
- 2) Make the stem as brief as possible. Avoid putting irrelevant information in the stem.
- 3) Avoid negative words in the stem. Negatively phrased items require twice as much working memory as positively phrased items.
- 4) Avoid opinion-based items. Items must reflect well-known publicly supported facts, concepts, principals, procedures, and regulations.
- 5) Do not write trick items or attempt to confuse the examinee.
- 6) Avoid using the following; all, only, never, always, he, she, you, and not.
- 7) Do not use the same words in the response options as in the stem.

### Writing the response options

Responses should:

Be plausible  
Be grammatically consistent with the stem  
Be of approximately the same length  
Be structurally parallel  
Provide only one correct answer  
Avoid all or none of the above  
Incorrect answers called distractors should not be too obvious

- 1) Write distractors that are comparable in length, grammatical form and complexity to the correct answer.
- 2) Keep the options independent from each other. The options should not overlap. Overlapping options can give a clue to the examinee about the correct answer and the distractors.
- 3) Keep the options homogenous in content and grammatical structure.
- 4) Make the length (number of words) of the options approximately the same.
- 5) Spell out all acronyms.
- 6) Avoid options that give clues to the right answer.

#### Identifying the reference

In order to maintain a legally defensible examination, all items must have a reference cited. The reference must contain the topic of the stem and state the correct answer. The references used must be published in the public domain and readily available to anyone.

Each reference must have the following information as it is appropriate to the reference document (hard copy or Web Site link).

- 1) Full name of document
- 2) Author (s)
- 3) Version or volume number
- 4) Published date
- 5) Chapter or article number
- 6) Page number
- 7) Website address link directly to the document

#### IV. CPIP Knowledge Elements

The technical competency includes seven knowledge elements which are the basis for the examination. Each knowledge element contains an overview description followed by knowledge-of-statements pertaining to specific topics within each knowledge element.

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##### **Knowledge Element 1 - Product Development**

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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.

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###### *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

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##### **Knowledge Element 2 - Facilities and equipment**

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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).

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*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

*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

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**Knowledge Element 3 - Information systems**

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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

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**Knowledge Element 4 - Supply chain management**

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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

*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

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**Knowledge Element 5 - Production systems**

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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
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

## V. On-line item writing

The ISPE-Professional Certification Commission (PCC) has developed an Internet platform for SME item writers to access via password. The SME will be directed to a log-on screen by clicking on the <item writers> tab on the [www.ispe-pcc.org](http://www.ispe-pcc.org) homepage. Each SME will have a unique password that is time sensitive.

Upon log-in the SME will view an item writing template. The template is filled in by the SME with the stem, options, key, and reference information. When the SME is finished writing the item, the <send> button is clicked and the item is sent to the CPIP item bank in a secure server. The SME will then view a new item writing template for writing the next item. This process is repeated until the SME logs off to end the item writing session.

The use of this template will be discussed during the item writing workshop.