

A Supplement to May/June 2006

PHARMACEUTICAL ENGINEERING

THE OFFICIAL
MAGAZINE OF
ISPE

Developing and Implementing
a Certification Program
to Drive Change in the
Pharmaceutical Industry



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ENGINEERING PHARMACEUTICAL INNOVATION



This article describes the credential development process utilized by the ISPE-PCC and the results obtained from the CPIP™ international practice analysis.

Developing and Implementing a Certification Program to Drive Change in the Pharmaceutical Industry

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Purpose and Context

The global pharmaceutical industry is facing needed change to improve drug product safety, quality, and consumer cost effectiveness while providing new drug therapies to the market more quickly and in a streamlined manner. Government regulators support this movement and encourage new science- and risk-based innovative approaches for drug product development, manufacturing, and distribution. This was emphasized by Janet Woodcock, MD, Deputy Commissioner for Operations, U.S. Food and Drug Administration (FDA), during her keynote address at the International Society for Pharmaceutical Engineering (ISPE) Annual Meeting (November 7, 2005).

To facilitate change in the industry, the ISPE, a not-for-profit, membership-based organization with a global membership of 23,000, has worked with government regulators, academia, and pharmaceutical industry stakeholders. Initiatives include collaboration with the University of Florida and the North Carolina Community College System to develop curricula to train a biotechnology workforce, and co-sponsorship of good manufacturing practices (GMP) workshops in China with the USFDA and Peking University (see www.ispe.org for descriptions of these activities).

In 2004, ISPE formed the ISPE Professional Certification Commission (ISPE-PCC) to govern the development and administration of credentialing programs for pharmaceutical industry professionals. The ISPE-PCC maintains autonomy and administrative independence from the ISPE International Board of Directors regarding credentialing decisions and is composed of 14 Commissioners representing Asia,

Oceania, Europe, and North America. The first group of Commissioners (serving terms of 1, 2, or 3 years), represents large and small global pharmaceutical organizations as well as academic and regulatory stakeholders. The Commissioners each have more than 25 years experience in the industry and collectively embody pharmaceutical industry and biotechnology practice, from drug product development through manufacturing.

The ISPE-PCC mission statement is twofold:

- To serve the global pharmaceutical and biotechnology industry by establishing competency standards for professionals involved in drug product development through manufacturing
- To elevate the status of industry professionals, provide employers with competent workers, facilitate development and manufacturing innovation, and enhance drug product quality

Recognizing the eminent challenges associated with industry innovation, the ISPE-PCC set out to develop and implement a pharmaceutical industry credential, the Certified Pharmaceutical Industry Professional™ (CPIP™), for professionals who demonstrate the competencies and knowledge required to become the “change agents” needed to realize the vision of the industry’s leaders assembled within the ISPE-PCC.

The purpose of this article is to describe the identification and validation of those competencies and the underlying knowledge base.

Development of a Description of the Pharmaceutical Professional

The ISPE-PCC was charged with developing and validating a contemporary description of a pharmaceutical industry professional that was consistent with the mission of the ISPE-PCC and its goal of developing a certification program that would positively impact the profession.

Background Work of the ISPE-PCC

The initial task of the ISPE-PCC was to operationalize the vision of the CPIP™; that is, to create a narrative description of what these professionals can do and know in terms of both depth and breadth of subject-matter expertise.

To facilitate the development of the narrative description, the Commissioners participated in a critical-incidents analysis process whereby they interviewed 11 managers and technology experts from the industry to understand how these professionals went about solving a realistic problem. In analyzing their responses, the Commissioners identified as many as 17 knowledge and 7 skill sets. They described a professional capable of:

- Identifying and analyzing problems, including problems that were both internal and external to the experts' areas of immediate responsibility and/or expertise;
- Pinpointing causes;
- Generating and evaluating alternate solutions;
- Demonstrating techniques for resolving problems, including the conduct of risk analyses; and
- Communicating across various disciplines within the organization.

Moreover, the narrative description included a competency component that highlighted a fully engaged individual—one with a “get it done” attitude, able to take action and work

across many disciplines in order to resolve situations.

The narrative description articulated by the Commissioners provided the framework for the next effort, which was to codify the competencies of the pharmaceutical industry professional, including all of the key knowledge and skill elements that would be expected to be in the CPIP™-credential holder's toolbox.

Refining the Vision

In August 2005, the ISPE-PCC contracted with Professional Examination Service (PES) to enhance and validate the narrative description of practice that had been developed by the members of the ISPE-PCC. The conduct of the study to develop and validate the practice description complied with current testing and measurement requirements for the validation of certification and licensure examinations. The overall process is described in the 1999 revision of the *Standards for Educational and Psychological Testing* (AERA/NCME/ APA) and the *Guidelines for the Development, Use, and Evaluation of Credentialing Programs* (PES, 1995). The work products of the study were consistent with the requirements set forth in ISO/IEC 17024, *Conformity assessment—General requirements for bodies operating certification of persons* (ISO, 2003). The documents emphasize the concept of content validity and the need to conduct an analysis of practice to ensure that what is assessed is required for competent performance and serves a public protection function. Practice analysis becomes an important basis by which a professional association or credentialing agency such as the ISPE-PCC establishes, maintains, and defends the validity of its credentialing program requirements, in general, and its assessment program, specifically.

Using the preliminary results obtained by the members of ISPE-PCC, the Commissioners developed a revised description of professional practice at a 2-day meeting of the ISPE-

Competency	Components	
Technical Competency	Elements and # of Knowledge Statements	#
Technical Knowledge	1. Product development	13
	2. Facilities and equipment	17
	3. Information systems	3
	4. Supply chain management	10
	5. Production systems	14
	6. Regulatory compliance (includes drugs, environmental, health and safety)	7
	7. Quality systems	7
Non-Technical Competency	Category Sets (Exemplars) and # of Behavioral Descriptors	#
Leadership and Professionalism	1. Leadership	7
	2. Decision making	5
	3. Communications and interpersonal behaviors	4
	4. Professional development	2
	5. Professional conduct	1
Integration/Innovation/Change Advocacy	1. Innovation and problem solving	5
	2. Cross-functional integration	5
	3. Risk-based, cost-effective approaches	3
Quality and Continuous Improvement Focus	1. Continuous improvement mindset	5
	2. Quality by design	3

Exhibit 1. Framework and Components.

Competency 1 – Technical Knowledge	
Knowledge Element 1 – Product Development	
<p>Formulation, Clinical Phases, and Manufacture</p> <ol style="list-style-type: none"> 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 <p>Technology Transfer</p> <ol style="list-style-type: none"> 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 <p>Production Scale-Up and Optimization</p> <ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 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 <p>Operational Economics</p> <ol style="list-style-type: none"> 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 <p>Warehouse and Distribution Management</p> <ol style="list-style-type: none"> 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 – Facilities and Equipment	
<p>Design and Construction/Installation</p> <ol style="list-style-type: none"> 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 <p>Commissioning and Qualification as a Risk Management Strategy</p> <ol style="list-style-type: none"> 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 <p>Operation and Maintenance</p> <ol style="list-style-type: none"> 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 <p>Controls and Automation</p> <ol style="list-style-type: none"> 16. Knowledge of building management systems 17. Knowledge of types of process automation and associated controls 	<p>Production Unit Operations – Drug (small molecule) and Biologics</p> <ol style="list-style-type: none"> 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 <p>Production Management</p> <ol style="list-style-type: none"> 7. Knowledge of production management 8. Knowledge of storage requirements, production logistics, and RFID 9. Knowledge of environmental conditions, security, and status requirements <p>Production Control</p> <ol style="list-style-type: none"> 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 3 – Information Systems	
<ol style="list-style-type: none"> 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 [ERP] or manufacturing resource planning/material requirement planning [MRP]) 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 	<p>Knowledge Element 5 – Production Systems</p> <p>Production Management</p> <ol style="list-style-type: none"> 7. Knowledge of production management 8. Knowledge of storage requirements, production logistics, and RFID 9. Knowledge of environmental conditions, security, and status requirements <p>Production Control</p> <ol style="list-style-type: none"> 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 4 – Supply Chain Management	
<p>Materials Management</p> <ol style="list-style-type: none"> 1. Knowledge of the key components of the supply chain 	<p>Knowledge Element 6 – Regulatory Compliance (includes drugs, environmental, health and safety)</p> <p>Government Regulations</p> <ol style="list-style-type: none"> 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 <p>Standards, Practices, and Guides</p> <ol style="list-style-type: none"> 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	
<p>Risk Management and Quality Management System (QMS)</p> <ol style="list-style-type: none"> 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 <p>Systems Validation</p> <ol style="list-style-type: none"> 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 	

Exhibit 2. Technical Knowledge, including 7 Knowledge Elements, and 71 Knowledge Statements.

PCC, facilitated by PES, in September 2005. Their goal was to codify the attributes of the professional as well as the breadth and depth of the essential knowledge base, and to inform the process by which all key aspects of the CPIP™ program were to be developed and implemented.

After detailed discussions, the Commissioners crafted an organizing framework for the practice description, including one technical competency and three non-technical competencies. The technical competency was structured into knowledge elements and knowledge statements, and the three non-technical competencies were structured into sets of competencies (exemplars) and behavioral descriptors. Key questions guided the development of the practice description:

- Does the practice description include a comprehensive list of the knowledge required and the skills demonstrated by pharmaceutical industry professionals?
- Is each aspect of the description clear and concise?, and
- Does the practice description address in all key aspects the narrative description developed by the Commissioners?

During the meeting, the Commissioners identified potential gaps in the representation of subject-matter experts (SMEs) contributing to the development of the practice description and identified specific *categories* of individuals to fill the gaps; for example, representatives from Europe and Japan, and experts in supply chain management and information database management. Subsequently, the Commissioners nominated more than 60 additional SMEs to contribute to the refinement of the practice description, including experienced industry professionals representing all areas of expertise from drug product development through manufacturing, as well as academics, regulators, and other key stakeholders representing the global pharmaceutical industry.

Following the September 2005 meeting of the ISPE-PCC, PES implemented two complementary data-collection initiatives to augment the practice description: an independent review of the description and critical-incident interviews to verify the comprehensiveness of the description. Twelve SMEs participated in the independent review, and 18 SMEs participated in the critical-incident interviews. Feedback from the SMEs participating in the independent review and the critical-incident interviews was summarized by PES and the results were used by the Commissioners at a follow-up meeting in November 2005, at which time a final description of professional practice was drafted. Exhibit 1 contains an outline of the framework for the description of practice, including all key components.

Exhibit 2 includes a list of the 71 technical knowledge statements related to the technical competency—*Technical knowledge*, and Exhibit 3 includes a list of the 40 behavioral descriptors related to the three non technical competencies—*Leadership and professionalism, Integration/Innovation/Change Advocacy, and Quality and Continuous Improvement Focus*.

Competency 2 – Leadership and Professionalism
<p>Leadership</p> <ol style="list-style-type: none"> 1. Leads by example, delegates appropriately, and commits self and team to achievement of goals 2. Creates an environment that motivates and enables innovation and high performance 3. Recognizes knowledge gaps and facilitates their resolution 4. Encourages others to evaluate their work and consider alternatives to the status quo 5. Encourages open feedback on own performance 6. Values cultural differences and uses effective dynamics and motivation within the business context 7. Conceptualizes and thinks strategically <p>Decision Making</p> <ol style="list-style-type: none"> 8. Defines authority, responsibility, and accountability for decision making 9. Facilitates broad and innovative thinking and fosters an environment for debate while participating in interdisciplinary teams 10. Demonstrates meeting management skills 11. Facilitates effective decision making 12. Assumes accountability for performance of the team members and decision making <p>Communications and Interpersonal Behaviors</p> <ol style="list-style-type: none"> 13. Communicates clear, concise, accurate information in timely way 14. Uses critical analysis tools to ask the right questions 15. Adapts reports and presentations to intended audience 16. Demonstrates respect for people, diversity of thought and ideas <p>Professional Development</p> <ol style="list-style-type: none"> 17. Stays current with industry and regulatory trends and applies this learning to the benefit of customers and the organization 18. Shares knowledge through mentoring and coaching of others <p>Professional Conduct</p> <ol style="list-style-type: none"> 19. Adheres to industry, ethical, and professional standards
Competency 3 – Integration/Innovation/Change Advocacy
<p>Innovation and Problem Solving</p> <ol style="list-style-type: none"> 1. Defines and formulates problems within a clear purpose, frame of reference and scope 2. Collects, selects, verifies, and evaluates information relevant to the defined problem 3. Chooses the appropriate statistical and management tools to analyze data patterns, relationships, and trends 4. Considers alternative solutions and stimulates innovation 5. Identifies and uses techniques from other industries that are applicable to pharmaceutical industry <p>Cross-Functional Integration</p> <ol style="list-style-type: none"> 6. Ensures potential changes take into account all possible upstream and/or downstream effects, both short and long term 7. Draws on knowledge, tools, and resources from within and outside the industry for possible solutions 8. Benchmarks best practices across industry 9. Identifies key steps, milestones, critical systems, and organizational relationships; and uses project management skills that are needed for success 10. Builds support with stakeholders and team members <p>Risk-Based, Cost-Effective Approaches</p> <ol style="list-style-type: none"> 11. Identifies, recommends and evaluates enhancements, including policy, program and process changes to effect efficiency and significant cost containment or savings 12. Recognizes issues that could impact the business and sets priorities for action 13. Utilizes risk-based management for products and processes
Competency 4 – Quality and Continuous Improvement Focus
<p>Continuous Improvement Mindset</p> <ol style="list-style-type: none"> 1. Acts as a change agent 2. Anticipates where problems are likely to arise and takes preventative action 3. Conducts reviews of existing systems, processes and controls within the organization to identify and drive opportunities for continuous improvement 4. Applies knowledge of regulatory requirements and industry best practices to develop pragmatic interpretations and approaches based on science and sound analysis 5. Strives for harmonization to enable more efficient global operations <p>Quality by Design</p> <ol style="list-style-type: none"> 6. Understands systems, products, and processes at a mechanistic level and designs quality from the outset 7. Promotes a quality mindset as opposed to one of compliance 8. Incorporates risk-based prioritization when involved with quality initiatives

Exhibit 3. *Leadership and Professionalism, Integration/Innovation/Change Advocacy, and Quality and Continuous Improvement Focus*, including 10 Competency Sets, and 40 Behavioral Descriptors.

Description of Practice	Version 1	Version 2	Version 3
Technical Competency – Technical Knowledge: 65 knowledge statements			
Frequency Ratings	✓		
Importance Ratings		✓	
Proficiency level Ratings			✓
Open-ended questions about Knowledge statements	✓	✓	✓
Technical Knowledge: 7 Elements			
% of Time	✓	✓	✓
Importance	✓	✓	✓
Non-Technical Competencies – Leadership and Professionalism, Integration/Innovation/Change Advocacy, and Quality and Continuous Improvement Focus: 40 behavioral descriptors			
Frequency Ratings	✓		
Importance Ratings		✓	
Essential Ratings			✓
Non-Technical Competencies – Leadership and Professionalism, Integration/Innovation/Change Advocacy, and Quality and Continuous Improvement Focus: 10 competencies sets			
Acquisition Ratings	✓	✓	✓
Verification Ratings	✓	✓	✓
Demographic and Professional Questions	✓	✓	✓
Open-ended Questions			
The value of the development of the ISPE-PCC credential	✓	✓	✓
Knowledge and skills recently acquired	✓	✓	✓
Changes to occur over the next three years	✓	✓	✓

Exhibit 4. Content of ISPE PCC Practice Analysis Survey Versions.

Validation of the Practice Description

In order to validate the description of professional practice developed by the ISPE-PCC, a large-scale survey was conducted. First, a draft survey was developed by PES and reviewed and revised by the Commissioners. Second, the survey was piloted tested by 11 SMEs nominated by the ISPE-PCC. Results of the pilot test were used to clarify the instructions, revise the rating scales, and augment the description of professional practice. Then, ISPE-PCC staff and a subset of Commissioners reviewed and finalized the survey instrument.

The survey included multiple sections that facilitated quantitative and qualitative data collection. Respondents rated:

- the frequency, importance, and proficiency level of each knowledge statement;
- the importance and percent of time spent in association with each knowledge element;
- the frequency, importance, and essentiality of each behavioral descriptor; and
- the verification and acquisition of each competency set (exemplar).

Respondents were also given the opportunity to provide open-ended comments regarding the comprehensiveness of the description of professional practice, and to respond to questions about the value of the proposed certification initiative.

To reduce the time required to complete the survey, three

versions of the survey were created—each containing all of the components of the practice description but a subset of the rating scales applied to two of the four components. Exhibit 4 contains an outline for the contents of each version of the survey, and Exhibit 5 contains a description of the rating scales used.

Results Related To the Validation Survey

The validation survey was emailed to a sample of 1200 pharmaceutical industry professionals selected from a list of over 4500 professionals with 5 to 15 years of pharmaceutical-industry experience included in the ISPE database. A two-stage sampling plan was implemented so as to ensure (a) the representation of SMEs from Asia/Pacific Islands, Europe, and North America, and (b) participants with expertise in each of the seven knowledge elements.

Each member of the sample received an email invitation from the ISPE-PCC in early January 2006, including a cover

Section 1	65 Technical Knowledge Statements
Frequency	How frequently do you use this knowledge? <i>1 = Never, 2 = Rarely, 3 = Occasionally, 4 = Frequently, or 5 = Very frequently</i>
Importance	How important is this knowledge in producing a quality product? <i>1 = Not important, 2 = Minimally important, 3 = Moderately important, or 4 = Highly important</i>
Proficiency Level	Which proficiency level best represents your usage of this knowledge? <i>Not used in practice, General awareness and background, Comprehension, or Mastery</i>
Section 2	7 Technical Knowledge Elements
% of Time	Overall, what percentage of your work time required this knowledge?
Importance	How important is this knowledge to individuals functioning at the level of a newly ISPE-PCC credentialed professional? <i>1 = Not important, 2 = Minimally important, 3 = Moderately important, or 4 = Highly important</i>
Section 3	40 Behavioral Descriptors related to Competencies
Frequency	How frequently do you demonstrate this competency? <i>1 = Never, 2 = Rarely, 3 = Occasionally, 4 = Frequently, or 5 = Very frequently</i>
Importance	How important is this competency in producing a quality product? <i>1 = Not important, 2 = Minimally important, 3 = Moderately important, or 4 = Highly important</i>
Essential	Is it essential that a newly ISPE-PCC credentialed professional demonstrate this competency? <i>Yes (Essential) or No (Not essential)</i>
Section 4	10 Competencies Sets (Exemplars)
Acquisition	At what point should the competencies in this set be acquired? <i>Never (The competencies in this set are not necessary) Primarily before ISPE-PCC certification or Primarily after ISPE-PCC certification</i>
Verification	In your professional judgment, how should this set of competencies be validated? Experience: <i>Verified through a practical experience questionnaire</i> Education: <i>Verified through education-related performance</i> Exam: <i>Verified through formal assessment</i>

Exhibit 5. Survey Rating Scales.

note describing the credentialing mission of the ISPE-PCC, and signed by the ISPE Director of Professional Certification. The email included a unique URL, linked to the web-based survey. Special features of the survey ensured that respondents could start and stop the survey, as necessary, and that they were randomly routed through one of the three versions. As an incentive, participants completing the survey were offered the chance to participate in a drawing for one of seven prizes. Two reminder emails were sent to each participant not previously completing the survey approximately 5 business days after the invitation email and the subsequent reminder.

In mid-February 2006, the ISPE-PCC met for 2 days to review the results of the validation survey and develop recommendations related to the development and implementation of a certification program for pharmaceutical professionals, if warranted by the results of the survey.

Demographic and Professional Characteristics of the Respondents

The overall response rate for the survey was 17%—relatively high given that a certification program did not exist at the time of the survey and the potential participants in the sample may not have been aware of the ISPE-PCC's intentions regarding the development of a certification program.

Consistent with the sampling plan, 56% of the respondents worked in North or South America, 35% in Europe or Africa, and 10% in Asia/Pacific Islands. About two thirds of the respondents indicated that they had worked in the industry from 6 to 15 years—reflecting the experience level of the target audience for the certification. About 80% of the respondents had earned either a Bachelor's degree or a Master's degree, while 10% had earned a doctorate.

Slightly more than one half of the respondents worked in organizations with fewer than 500 employees. Respondents were most likely to describe themselves as working in validation (24%) or engineering and technical support (20%), and less likely to indicate that they worked in project management (16%) or regulatory/compliance/QA (11%). Two thirds of the sample described themselves as working in traditional pharmaceuticals, biopharmaceuticals/biotechnology, or consulting. When asked to indicate their primary area of expertise, the responses of the survey respondents were virtually identical to the profiles of the nearly 30,000 individuals in the ISPE database.

The respondents to the survey were more likely to spend significant amounts of time (64%) in pharmaceutical product manufacturing and less time in pharmaceutical product development (17%). A closer inspection of the time estimates revealed that 25% of the respondents spent no time in product development, whereas only 6% of the respondents spent no time in product manufacturing.

Respondents indicated that they had expertise in one or more of the seven technical knowledge elements identified in connection with the *Technical Knowledge* competency area—providing some indication that these elements might provide a useful mechanism for describing professional practice.

	n	%
Product Development	24	18%
Facilities and Equipment	98	73%
Information Systems	25	19%
Supply Chain Management	7	5%
Production Systems	62	46%
Regulatory Compliance (includes drugs, environmental, health and safety)	49	36%
Quality Systems	58	43%
Other	7	5%

Table A. Knowledge Elements Expertise.

Table A indicates the percentage of respondents indicating expertise in each of the seven technical knowledge elements.

Finally, the ISPE-PCC reviewed the demographic and professional analyses of the respondents and confirmed that these individuals were similar to the membership of the ISPE and to other pharmaceutical professionals in regard to every key demographic and professional variable.

Quantitative and Qualitative Results Related to Competencies

Quantitative and qualitative analyses were performed on the sections of the survey related to the *Technical Knowledge* competency and the three non-technical competencies (*Leadership and Professionalism*, *Integration / Innovation / Change Advocacy*, and *Quality and Continuous Improvement Focus*) using the survey ratings of the total sample of respondents—regardless of the survey version to which they had responded.

Results Related to Technical Knowledge Competency—Knowledge Elements and Knowledge Statements

For each of the seven Technical Knowledge elements, the mean, range, and standard deviation were reported for the % of Time and Importance scales. The knowledge element results are presented in Table B, which also includes the definition of each element. The percentage of time ratings show that, on average, respondents spent about 25% of their time calling upon knowledge related to Facilities and equipment. They spent somewhat less time calling upon knowledge related to Production systems, Quality systems, and Regulatory compliance (includes drugs, environmental, health and safety), and even less time with regard to the remaining three knowledge elements, Information systems, Product development, and Supply chain management.

The knowledge elements related to Facilities and equipment, Production systems, Regulatory compliance, and Quality systems received an average rating indicating that the knowledge associated with these elements was at least moderately-to-highly important to individuals functioning at the level of a newly credentialed professional. The remaining four knowledge elements received an average importance rating indicating that the related knowledge was at least minimally-to-moderately important.

For each of the 65 knowledge statements, the mean and standard deviation of the respondents' ratings were reported for the Importance and Frequency rating scales, along with

	% of Time	Importance
1. Product Development: 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.	8.9% 0 – 100 (14.8)	2.8 1 – 4 (.8)
2. Facilities and Equipment: 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).	24.8% 0 – 90 (19.7)	3.5 1 – 4 (.7)
3. Information Systems: 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.	9.3% 0 – 60 (10.2)	2.8 1 – 4 (.7)
4. Supply Chain Management: 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.	5.5% 0 – 100 (10.2)	2.5 1 – 4 (.7)
5. Production Systems: 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.	18.7% 0 – 80 (16.0)	3.4 1 – 4 (.7)
6. Regulatory Compliance (includes drugs, environmental, health and safety): 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.	15.8% 0 – 75 (12.4)	3.4 1 – 4 (.7)
7. Quality Systems: 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.	16.9% 0 – 70 (13.7)	3.4 1 – 4 (.7)

Table B. Mean, Range, and (Standard Deviation) of % of Time and Importance.

the percentage of respondents indicating each scale point on the *Proficiency* scale. With few exceptions, the average rating of each knowledge statement indicated that the knowledge was moderately-to-highly important to producing a quality product. The average frequency that knowledge was used was more varied. In general, knowledge related to Facilities and equipment, Information systems, Production systems, Regulatory compliance, and Quality systems was called upon more frequently than knowledge associated with Product development and Supply chain management. The knowledge statements with the highest frequency ratings were in the areas of Regulatory compliance and Quality systems and received among the highest importance ratings.

The percentage of respondents indicating each scale point on the *Proficiency* scale indicated that each of the knowledge statements delineated in connection with five of the seven knowledge elements was used at some level by more than 80% of the respondents. Only in the areas of Product development and Supply chain management did as many as 24% and 49% of the respondents, respectively, indicate that the related knowledge was not used in professional practice. Respondents indicated that knowledge related to Product development, Regulatory compliance, and Quality systems was most frequently used at the Comprehension level; and knowledge related to Facilities and equipment was most frequently used at the Comprehension and Mastery levels.

Respondents were provided the opportunity to identify additional knowledge that may have been omitted from the description of practice. A review of all the qualitative comments of the respondents indicated that the delineation of 65 knowledge statements associated with the *Technical Knowledge* competency was comprehensive.

Results Related to Leadership and Professionalism, Integration/Innovation/Change Advocacy, and Quality and Continuous Improvement Focus Competencies—Competency Sets (Exemplars) and Behavioral Descriptors

For each of the 10 competency sets, the mean and standard deviation of the respondents' ratings were reported for the *Acquisition* and *Verification* rating scales. As seen in Table C, a majority of the respondents indicated that 9 of the 10 sets of competencies be acquired primarily *before* certification. In the case of one competency set, Cross functional integration, associated with the *Integration/Innovation/Change Advocacy* competency, the respondents were about as likely to indicate that this set be acquired primarily *before* and primarily *after* certification. The verification ratings of the respondents indicated that they supported the verification of the non-technical competencies through multiple methods, including experience, education, and examination. In general, respondents were most likely to support the verification of the sets of competencies related to *Leadership and Professionalism* through experience requirements, and the sets of competencies related to both *Integration/Innovation/Change Advocacy* and *Quality and Continuous Improvement Focus* through experience and education requirements. Thirty percent or more of the respondents indicated that three sets of competencies could be verified through examination requirements.

For each of the 40 behavioral descriptors, the mean and standard deviation of the respondents' ratings were reported for the *Frequency* and *Importance* rating scales, along with the percent of respondents indicating each scale point on the *Essential* scale. The average frequency rating indicated that 39 of 40 behavioral descriptors were demonstrated at least

occasionally. Behavioral descriptors associated with *Leadership and Professionalism* were most likely to be demonstrated frequently-to-very frequently, and behavioral descriptors associated with *Quality and Continuous Improvement Focus* were most likely to be demonstrated occasionally-to-frequently.

Without exception, the average importance rating for each behavioral descriptor indicated that it was moderately-to-highly important to producing a quality product. In general, two thirds or more of the respondents indicated that each behavioral descriptor should be demonstrated by newly credentialed professionals.

Results Related to Open-Ended Questions—The Value of Certification, Recently Acquired Knowledge or Skills, and Changes in the Profession

Respondents identified the possible benefits of certification. For the profession as a whole, they indicated that the implementation of a credential would establish and clarify a uniform standard for the profession, drive innovation, contribute to the development of “best practices,” and lead to an internationally recognized benchmark for pharmaceutical professionals. On an individual level, they indicated that the credential would facilitate hiring, recruiting, and job mobility, while providing a useful tool for understanding one’s own knowledge base.

Members of the ISPE-PCC reviewed the open-ended comments made by the respondents regarding recently acquired knowledge or skills. Respondents were most likely to have participated in learning related to regulatory standards; technical and information systems; risk analysis and risk management; project management, leadership, and quality management; key performance indicators, process improvement, and process control; safety; facilities; non-pharmaceutical manufacturing processes; business knowledge, finance, and business strategy; and problem solving.

Members of the ISPE-PCC also reviewed the respondents’ comments regarding industry changes they perceived would occur in the next three years.

- Respondents were most likely to describe the increased focus on global regulatory health authorities’ (RHAs) requirements and process analytical technology (PAT) concepts;
- Respondents were also likely to indicate an increased focus on: accountability for capital effectiveness; increased process-improvement, lean manufacturing, Six-Sigma, continuous improvement; automation; and validation requirements.
- Respondents indicated that the industry will face downsizing and cost cutting at the same time as it contends with the drive for enhanced production to move the industry forward.

Results Related to Hypothetical Specifications for the Assessment of the Technical Knowledge Competency

Assessment specifications are outlines or blueprints that are used to construct certification examinations. In February, 2006, at a 2-day meeting of the ISPE-PCC, the Commissioners reviewed all of the quantitative and qualitative results of the validation survey and a set of hypothetical assessment specifications. The hypothetical assessment specifications were derived by weighting equally the percentage of time and the importance ratings of the respondents on the seven knowledge elements associated with the *Technical Knowledge* competency.

Based on extensive discussions of the survey results, final assessment specifications were developed for the proposed certification program. In proposing recommendations for adjusting the hypothetical assessment specifications, the Commissioners considered the following:

Non-Technical Competencies and Competency Sets (Exemplars)	Acquisition			Verification		
	Never	Primarily before ISPE PCC certification	Primarily after ISPE PCC certification	Experience	Education	Examination
	%	%	%	%	%	%
<i>Leadership and Professionalism</i>						
Leadership	8%	58%	34%	92%	34%	6%
Decision making	4%	73%	23%	84%	37%	18%
Communications and interpersonal behaviors	5%	76%	20%	79%	47%	12%
Professional development	2%	60%	39%	63%	68%	30%
Professional conduct	2%	79%	18%	79%	33%	17%
<i>Integration/Innovation/Change Advocacy</i>						
Innovation and problem solving	2%	68%	30%	68%	50%	24%
Cross-functional integration	5%	48%	47%	73%	41%	15%
Risk-based, cost-effective approaches	3%	60%	37%	52%	59%	39%
<i>Quality and Continuous Improvement Focus</i>						
Continuous improvement mindset	3%	63%	34%	75%	47%	22%
Quality by design	1%	74%	25%	54%	60%	36%

Table C. Acquisition and Verification Ratings for Competency Sets (Exemplars).

- the potential overlap between knowledge elements (for example, Product development, Facilities and Equipment, and Production systems; Regulatory compliance and Quality assurance);
- the impact of the under-representation of respondents engaged in product development;
- the impact of the over-representation of respondents engaged in activities related to facilities and equipment;
- the open-ended comments of the respondents in regard to upcoming changes in practice; and
- the mission statement of the ISPE-PCC regarding fostering industry innovation and quality improvement.

ISPE-PCC Decisions Regarding the Implementation of the Certification Program

After much discussion, the Commissioners determined that the sample of survey respondents represented a robust cross-section of professionals in the pharmaceutical industry, and that their quantitative ratings and qualitative comments were consistent with how industry professionals currently function. The Commissioners discussed the differences between the empirical ratings and ISPE-PCC's vision of professional practice.

Then, the Commissioners identified both initial and ongoing requirements for the CPIP™ program candidates that were consistent with the vision of the ISPE-PCC. These requirements were crafted so as to align with the results of the validation survey and acknowledge the key role that both technical and non-technical competencies play in competent professional practice. Based on the practice analysis data collected and psychometrically analyzed, and tempered by the vision of the pharmaceutical industry professional needed to drive change in the profession, the ISPE-PCC established eligibility criteria and the form of assessment required for the CPIP™ credential.

Education

Based on all of the quantitative and qualitative ratings, the results of the validation survey strongly supported a focus on a scientifically-educated person. Accordingly, the Commissioners determined that all candidates for certification, regardless of geographical location, must demonstrate that they had earned at least a Bachelor's degree or globally equivalent university degree from an educational institution accredited by a generally recognized accrediting body (e.g.,

ABET, SACS, UK Science and Engineering Research Council).

Experience

Based on all of the quantitative and qualitative ratings, the results of the validation survey strongly supported a focus on technical as well as non-technical competencies. Accordingly, the Commissioners determined that candidates for the certification must document specific experiences that illustrate competency in each of the four major competency areas, in general, and a subset of competencies related to *each* major competency area, in particular.

- *Technical Knowledge*—via formal assessment;
- *Leadership and Professionalism*—experience in any 2 of the 4 competency sets: Leadership, Decision making, Communications and interpersonal behaviors, Professional development;
- *Integration/Innovation/Change Advocacy*— experience in any 2 of the 3 competency sets: Innovation and problem solving, Cross-functional integration, Risk-based, cost-effective approaches;
- *Quality and Continuous Improvement Focus*—experience in any 1 of 2 competency sets: Continuous improvement mindset, Quality by design.

In addition, the Commissioners determined that candidates with educational backgrounds in science, technology, engineering, or mathematics (STEM) must document 5 years of relevant pharmaceutical-related work experience, while candidates with non-STEM backgrounds must document 10 years of pharmaceutical-related work experience.

Examination

Based on all of the quantitative and qualitative ratings, the results of the validation survey strongly supported a focus on technical knowledge demonstrated in the context of both technical and non-technical situations. After being determined eligible by the ISPE-PCC, the CPIP™ candidate may register for the CPIP™ examination. The examination will cover the 7 knowledge elements associated with the *Technical Knowledge* competency. The CPIP™ credential will be awarded upon successfully passing the examination.

As shown in Table D, the final specifications for a written knowledge-based examination give greatest weight to two knowledge elements—Facilities and equipment (20%) and Production systems (21%); somewhat less weight to three knowledge elements—Quality systems (16%), Product development (14%), and Regulatory compliance (13%); and least weight to two knowledge elements—Information systems (8%) and Supply chain management (8%).

In considering the specific content of the written knowledge-based examination, the Commissioners determined that since all 71 knowledge statements had been validated, they

Technical Knowledge	% of Assessment
1. Product Development	14%
2. Facilities and Equipment	20%
3. Information Systems	8%
4. Supply Chain Management	8%
5. Production Systems	21%
6. Regulatory Compliance (includes drugs, environmental, health and safety)	13%
7. Quality Systems	16%
	100%

Table D. Assessment Specifications for Technical Knowledge.

might all be used as the basis of item writing and examination construction initiatives. Accordingly, all written knowledge-based examinations developed in connection with the proposed certification program will be identical with regard to the testing emphasis associated with each knowledge element, and will draw upon the entire knowledge base.

Commissioners discussed recertification requirements related to education, experience, and examination, and determined that these requirements should be developed and implemented in a manner that focuses on assuring the continuing competency and currency of the technical knowledge of the CPIP™.

Conclusion

Innovation is the new industry buzz word. The pharmaceutical industry and the professionals employed in it must be proactive in pursuing innovative concepts to improve overall drug product development and manufacturing efficiency and quality. The ISPE-PCC believes that recognition of “change agents” and certification of those professionals will become a catalyst for innovation. As technology advances and the global regulatory environment moves towards harmonization, the ISPE-PCC must respond to these stimuli by creating professional certification programs for enhancing the professional practitioners’ career and for the benefit of their employers. It will be key that the ISPE-PCC ensures the ongoing validity of its certification program requirements by examining academic, industry, and regulatory-environment drivers with an eye to the future. To that end, the ISPE-PCC will conduct an analysis of practice for the CPIP™ on a periodic cycle to keep pace with change.

References

1. American Educational Research Association, American Psychological Association, & National Council on Measurement in Education (1999). *Standards for Educational and Psychological Testing*. Washington, DC: American Psychological Association.
2. International Standard ISO/IEC 17024 (2003). *Conformity assessment—General requirements for bodies operating certification of persons*. Switzerland: ISO.
3. Professional Examination Service (1995). *Guidelines for the Development, Use, and Evaluation of Licensure and Credentialing Programs*. New York, NY: Author.
4. Woodcock, J. (7 November 2005). *Engineering pharmaceutical innovation...The next 25 years!* Plenary session at the annual meeting of the International Society of Pharmaceutical Engineers, Scottsdale, AZ.

Acknowledgement

The authors of this article would like to thank the ISPE-PCC Commissioners for their vision, guidance, and dedication in conducting this international practice analysis for the Certified Pharmaceutical Industry Professional™ (CPIP™).

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