CPIP(医薬専門技術者資格)

2008年12月ISPE日本本部冬季大会



ISPE 専門技術者認定責任者
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発表　ISPE国際本部理事
平地富安

目次

- CPIP™医薬専門技術者資格について
- 本資格の利点と利用
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- 学習ガイド
- 資格の更新
- www.ispe-pcc.org

ISPE Professional Certification Commission

CPIPについて

医薬専門技術者資格

適格性審査による資格認定

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CPIPの目的

- 製薬業界における専門能力の世界基準を設定
- 製薬業界技術者の流動化に対応
- 改革の主導や変化の促進に必要な知識とスキルを有する「変革の担い手となるべき人材」の認定

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CPIP資格について

多様な知識とスキル

臨床治験

スケール
アップ

技術移転

製品開発

商業生産

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CPIP資格について

役割

CPIP（製薬専門技術者）は、幅広い業界知識と経験を持ち、その知識とスキルを用いて高い対費用効果、リスクにベースドアプローチ、イノベーション、Quality by Design、継続的な改善を達成する。

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CPIP資格について

4つの適格性

- **＃1　技術知識**
- ＃2　リーダーシップおよび高い専門家としての意識
- ＃3　統合／改革／変革の提唱
- ＃4　品質と継続的改善の重視

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CPIP資格について

技術知識適格性としては、以下の知識を要する

1. 製品開発
2. 施設、設備機械
3. 情報システム
4. サプライチェーン・マネジメント
5. 生産システム
6. 規制遵守（医薬品、環境、労働衛生安全）
7. 品質システム

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CPIP資格について

適格性2（リーダーシップおよび専門家としての職業意識）としては以下のようなものがある

1．リーダーシップ
2．決断能力
3．コミュニケーションおよび対人能力
4．専門技術能力開発

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CPIP資格のメリットと利用方法

- 専門家として、または被雇用者として活用
- 業界において、または雇用者として活用

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CPIP資格のメリットと利用方法

専門家として、または被雇用者として活用

- 高い信頼性
- 世界基準の資格
- キャリアの流動性
- 競争での優位性
- 「社会的変化の担い手となるべき人材」としての認定
- 「再認定」による専門家としての継続的な成長

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CPIP資格のメリットと利用方法

CPIP資格は、個々の適格性と先見性のあるスキルを適用することが出来る、幅広い業界知識と経験を持っていることを証明する資格となる。

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CPIP資格のメリットと利用方法

業界において、または雇用者として活用

- 世界に通用する適格性基準
- 「変革の担い手となるべき人材」の証明と検証
- 将来性があり、品質や効率に大きな影響を及ぼす人材
- 人材採用基準

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CPIP資格のメリットと利用方法

雇用者は、多様な知識を持ち、その知識を業界の様々な分野に適用することができると認定されたCPIP資格所有者を雇用する事で恩恵を受けることができる。

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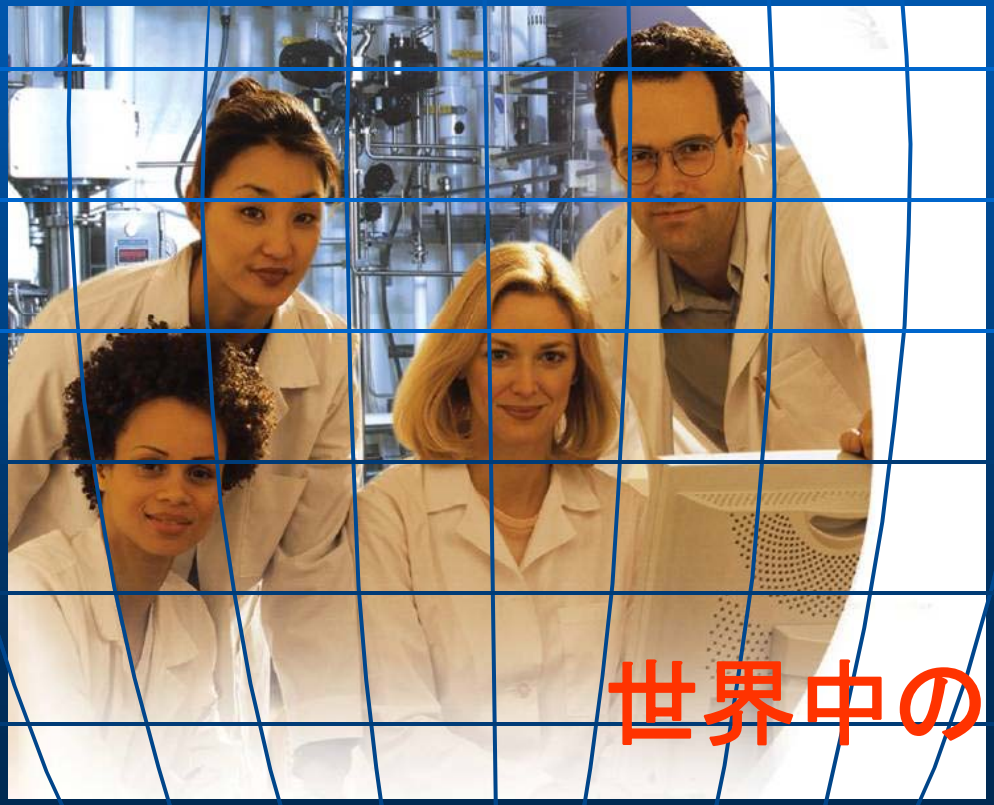
受験資格

誰でも受験できます

（ISPE会員又は非会員のいずれも可）



世界中のどこでも

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審査

出願者が受ける審査

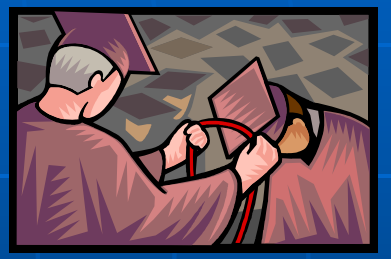
学　歴

＋

職務経験

＋

試　験



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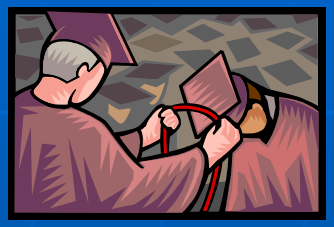
学　歴



大卒以上

科学（Science）
技術（Technical）
工学（Engineering）
数学（Math）

"STEM"

公認教育機関による学位

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職務経験

STEM（理系出身者）　＋　職務経験５年

Non-STEM（非理系出身者）　＋　職務経験１０年

以下に該当する職務経験

適格性 ＃２

適格性＃ ３

適格性＃ ４

９項目のうち、
５項目以上を
証明

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試　験

2009年3月／4月

2009年9月／10月

- 適格性1
- コンピュータによる試験
- 選択式の問題150問
- 試験会場制限事項

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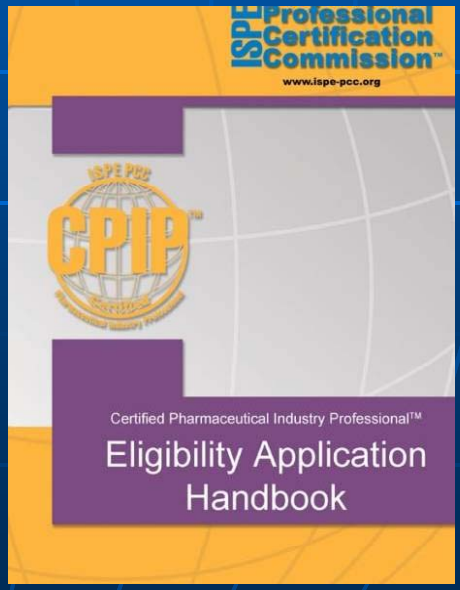
受験資格審査出願
書類

1.申請用紙CPIP-EA-1

調査票
学歴
受験費用支払方法



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受験資格審査出願
書類

2.申請用紙CPIP-EA-2

専門技術者としての職務経験

申請経験 / 模範例ごとに
用紙1式（5項目以上）

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受験資格審査出願

書類

3．推薦状（2通以上）

4．大学 / 短大の成績証明書原本

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受験資格審査出願費用（2008年）

ISPE会員

100.00ドル、または80.00ユーロ

非会員

200.00ドル、または160.00ユーロ

ISPE Professional Certification Commission

受験費用（2008年）

ISPE会員

300.00ドル、または240.00ユーロ

非会員

400.00ドル、または320.00ユーロ

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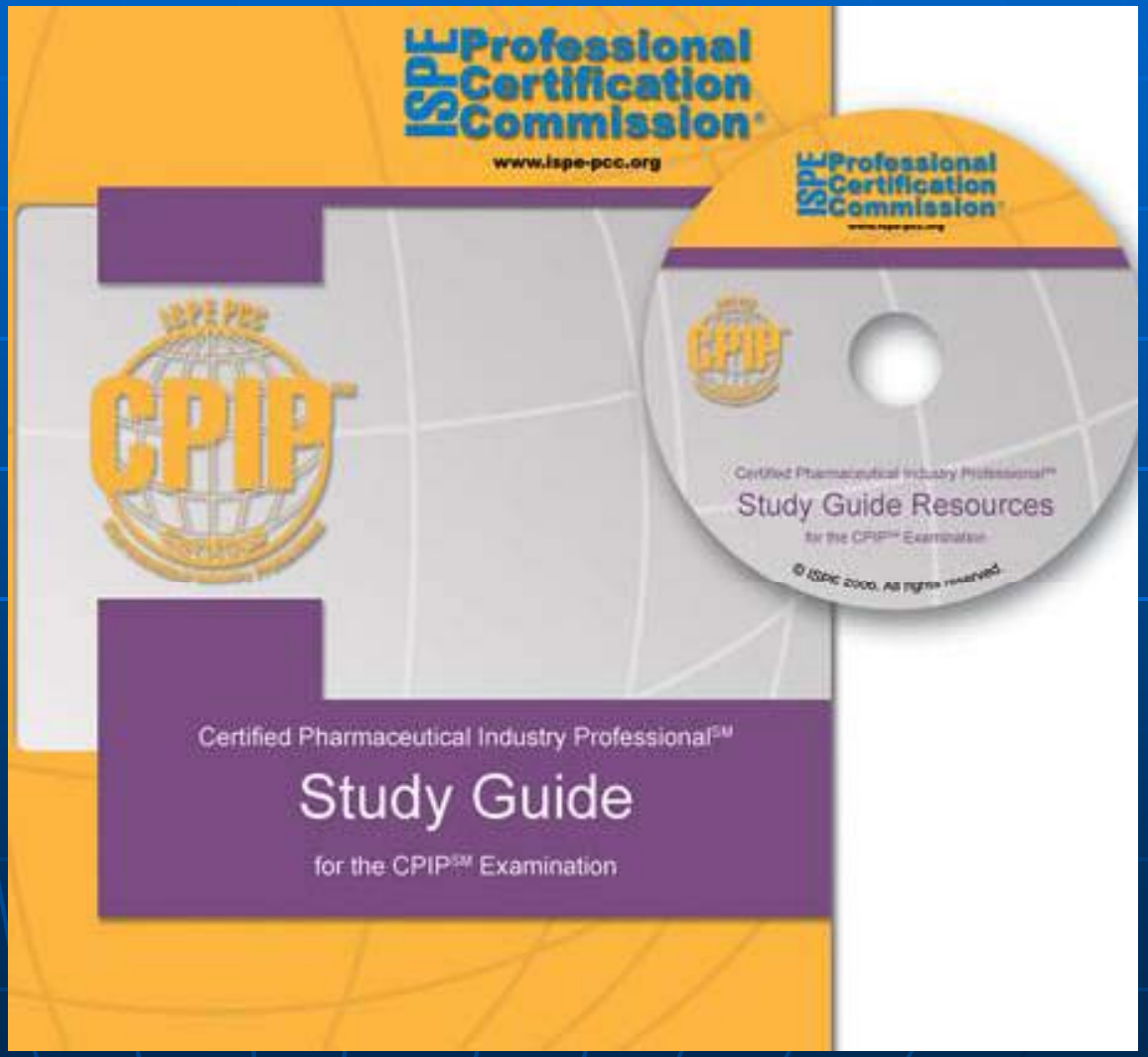
CPIP 学習ガイド

ISPE会員
40.00ドルまたは
32.00ユーロ

非会員
60.00ドルまたは
48.00ユーロ



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学習ガイド

I.　序文
II.　CPIP受験資格および試験
III. 学習ガイドについて
IV.　CPIP試験基準と内容の概要
V.　よくある質問とその回答
VI.　学習リソースおよび模擬試験問題と解答
（CD-ROM）

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学習ガイド

CD-ROM

- SME試験項目作成者が使用したリソース文書へのリンク（インターネット）
- 専門知識別リソースおよびリソースの種類
- 問題例とその解答25題

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資格の更新

CPIP継続認定要件プログラムの目的

- 有資格者のリーダーシップ、専門家としての　職業意識、改革、品質、継続的改善に　関わるスキルの維持を保証する
- 有資格者の最新の業界業務と行政規則に関する知識の維持を保証する

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資格の更新

- 3年ごと
- 職務経験
- 知識基盤の強化
- ポイント制

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資格の更新

- CPIP資格には、3年間の資格有効期限内に認定ポイントを60ポイント以上獲得し、倫理・職務に関するPCC規範の遵守継続に同意することが必要

プログラムの詳細は、ISPE-PCCウェブサイト上の「受験資格審査出願ハンドブック」で入手可能

www.ispe-pcc.org

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ISPE-PCCの使命

- 製造を通して医薬品開発に携わる専門家の適格性基準を設定することにより、世界中の医薬品およびバイオテクノロジー業界に貢献する

- 業界専門家の現状向上、雇用者への能力の高い職員の提供、開発と製造改革の推進、および医薬品品質の強化の実施

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www.ispe-pcc.org

または

www.ispe.org

医薬専門技術者資格

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Page

ISPE Professional Certification Commission

- PCC Home
- About PCC
- My PCC
- Certification Programs
- FAQs
- Committees
- Item Writing
- Contact Us
- E-Communities
- ISPE Home

Welcome to the ISPE-PCC

The ISPE Professional Certification Commission (ISPE-PCC), a governing body within the ISPE governance structure, is established to create certification programs that benefit the credential holder and their employers as well as government, academia, and the public health product consumer.

The ISPE-PCC has been granted and will maintain autonomy and administrative independence from the ISPE International Board of Directors pertaining to credentialing decisions. At a minimum, all decisions related to eligibility, standards, assessments, certification, recertification, and appeals are the sole responsibility of the PCC.

Prospective CPIP℠

About the CPIP

- How the CPIP Was Developed
- CPIP Overview

How the CPIP Benefits You

- Benefits

Employer

About the CPIP

- How the CPIP Was Developed
- CPIP Overview

How the CPIP Benefits Your Company/Employees

News

NEW! Practice Exam

NEW! Professional Experience Form Samples

NEW! CPIP Credentials Conferred to Industry Professionals

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Page

ISPE Home

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How the CPIP Benefits You

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- Industry Testimonials

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- CPIP Overview

How the CPIP Benefits Your Company/Employees

- Benefits
- Industry Testimonials

Help Your Employees Become CPIPs

- Easy Ways to Promote CPIP to Employees. Free Downloads (Flyer, Poster, E-mail/Web Site Content, and More ...)

News

NEW! Practice Exam

NEW! Professional Experience Form Samples

NEW! CPIP Credentials Conferred to Industry Professionals

CPIP Eligibility

- Eligibility Criteria and Fees
- Eligibility Application Handbook and Forms
- Professional Experience Form Samples

CPIP Recertification

- Recertification Criteria and Fees
- Recertification Application Handbook and Forms

CPIP Examination

- Exam Basis and Fees
- Exam Application Forms
- Study Guide
- Practice Exam

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製薬業界唯一の専門技術者資格

Fostering Innovation through demonstrated diversity

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CPIP-EA-2 Applicant Professional Experience (page 1 of 2)

Professional Experience (Please check one for each form submitted) *Submit this form with form CPIP-EA-1*
A minimum of five CPIP-EA-2 forms are required.

Competency 2 - Leadership and Professionalism
- ☐ Exemplar I – Leadership
- ☐ Exemplar II – Decision Making
- ☒ Exemplar III – Communications and Interpersonal Behaviors
- ☐ Exemplar IV – Professional Development

Competency 3 - Integration/Innovation/Change Advocacy
- ☐ Exemplar I – Innovation and Problem Solving
- ☐ Exemplar II – Cross-Functional Integration
- ☐ Exemplar III – Risk-Based, Cost-Effective Approaches

Competency 4 - Quality and Continuous Improvement Focus
- ☐ Exemplar I – Continuous Improvement Mindset
- ☐ Exemplar II – Quality by Design

Please complete entire section in English language (type or print clearly)

Date* 2000-2002 Applicant Name [redacted]
*Year(s) in which experience occurred Position Title [redacted]
Company Name [redacted]

Exemplar Experience Description

During these two years of experience, the most important activities were involved with validation and quality systems. I lead different and important projects, considering that the company is a consultant firm. The first project that I managed was in a Pharmaceutical facility from [redacted], where I carried out all the validation activities for the parenteral products plant. It was developed all the qualification protocols for areas, systems including water, steam, gases, compressed air and HVAC, considering domestic, FDA and European requirements. The protocols for all the manufacturing and packaging equipment were developed and executed (approximately 32 items), and process validation (media fill) was carried out. All these activities were presented to the Quality and Operation Managers of the Plant, and were audited by the worldwide auditors that the company had around the world. Also the information served to approve a sanitary audit by the [redacted] authority, helping to the firm to get the main purpose. I had continuous contact with the international heads of the company to give advances of the project, not only by e-mail, but also by phone and personally, doing different presentations in English and [redacted], according to requirements. Each week I had to send written reports and activities to be achieved for the next week according to the main program. Some changes were made to the program, due to some delays in the approval of protocols by the customers, and the different audits carried out. I had 12 people in charge. There were also given some courses of Good Validation Practices and Good Documentation Practices. The second project involved Commissioning and Validation activities lead for a medical device [redacted] company, located in [redacted]. I lead the development and execution of SAT's and qualification protocols, including computer system validation according to CFR 21 Part 11. I had 10 people in charge. I gave training in Good Validation Practices. I presented reports to the CEO of the company each week and I had to send written reports to headquarters in English. We applied risk management methodologies in the validation activities and acceptance criteria, considering the different tools presented in that time. Different kind of reports were developed according to the audience, one's for technical positions, auditors and other for director positions. The third project included the development of all the documentation system for a [redacted] company in [redacted]. There was done the main SOP'S to create the quality system, as well as the different registration forms to obtain records according to GMP regulations, considering domestic requirements. SAT's protocols were developed and executed as well as the Validation Master Plan. I had 7 people in my charge. I had meeting with all the suppliers and partners in the project, each week. The reports were in [redacted] and had to be given to the CEO of the company and Quality Assurance Director, in order to evaluate advances. Also I gave training in GMP Audits and

[redacted]

CPIP-EA-2 Application continued on the next page

CPIP Practice Exam 1

- 1
- Which of the following phases of a clinical trial may be conducted with normal volunteer subjects?
- A Phase 1
- B Phase 2
- C Phase 3
- D Phase 4
- 2
- Which of the following government regulations specifically defines the safe interaction of
- pharmaceutical employees with the materials they process?
- A USFDA 21 CFR Part 211
- B USRCRA 40 CFR Parts 260-281
- C USOSHA 29 CFR Part 1910
- D USFDA CFR Part 820
- 3
- Which of the following best describes the role of a laboratory information management system (LIMS) in a pharmaceutical company?
- A Ordering of laboratory supplies
- B Managing project timelines for laboratory equipment upgrades
- C Providing access to scientific reference materials for laboratory personnel
- D Managing the various laboratory data from sample log-in to reporting the results