2025 | CANDIDATE HANDBOOK

COUNCIL ON PHARMACY STANDARDS

Certification Examination

CIDSP

Certified Investigational Drug Services Pharmacist

Council on Pharmacy Standards

COUNCIL ON PHARMACY STANDARDS

CANDIDATE HANDBOOK

Recognition, Value, Expertise...

It is what certification is all about!

ABOUT CERTIFICATION

Competency-based certification allows pharmacists to demonstrate validated, practice-relevant knowledge in a defined specialty. Through CPS certification, candidates attest to professional accountability, lifelong learning, and safe, effective practice.

The Certification Commission for the Council on Pharmacy Standards (CC-CPS) is the independent body that designs, governs, and maintains CPS certification and recertification programs. CC-CPS operates at arm's length from CPS education and operations, with formal conflict-of-interest controls, documented firewalls, and term limits to preserve independence.

CC-CPS follows recognized best-practice frameworks, including ISO/IEC 17024, the Standards for Educational and Psychological Testing (AERA/APA/NCME), and guidance from ICE and NCCA.

TABLE OF CONTENTS

ELIGIBILITY CRITERIA

All eligibility criteria must be met at the time of application

CURRENT LICENSURE

Candidates must hold a Doctor of Pharmacy (Pharm.D.) or Bachelor of Science in Pharmacy (B.S. Pharm.) degree from a program accredited by the Accreditation Council for Pharmacy Education (ACPE). Graduates of programs outside of the U.S. must hold a degree deemed equivalent and/or possess a Foreign Pharmacy Graduate Examination Committee® (FPGEC) Certificate.

PRACTICE EXPERIENCE

Current/active unrestricted licensure as a pharmacist is required. An "unrestricted" license is not currently subject to any limitations, probation, or disciplinary action.

- **U.S. Licensed Pharmacists**: Must possess an active, unrestricted license to practice pharmacy in at least one U.S. state or territory.
- **International Pharmacists**: Must hold an active and unrestricted license in their country of practice. A certified English translation must be provided if the original license is not in English.

Candidates will need to upload their license or a printout of the verification that includes their name, license number, licensing state or country, and the date the license expires.

SPECIALTY QUALIFICATION

To ensure candidates have foundational knowledge in the specialty, one of the following two pathways must be met:

1. **Standard Pathway**: Completion of one year (12 months) of experience comprised of at least 2000 hours of practice time as a licensed pharmacist in one of the above exam specialties must be documented. **This is not an either/or requirement – both time and hours must be met.**
2. **Certificate Pathway**: The specialty experience requirement is met for candidates who hold an active certificate of completion from a nationally recognized provider in a related subject matter. This includes, but is not limited to, the completion of a relevant PGY residency, fellowship, certificate/training program, or a relevant graduate degree. Recognized providers include:
    - American Society of Health-System Pharmacists (ASHP)
    - American Pharmacists Association (APhA)
    - American College of Clinical Pharmacy (ACCP)
    - American Society of Consultant Pharmacists (ASCP)

RESOURCES

CPS Exam Candidates

Use the Study Guides & Preview Tests page as the official and most current source for all exam materials.

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How to find your materials

1. Visit **pharmacystandards.org/study-guides**.
2. Search by certification name or acronym (e.g., CPOM).
3. Open the items under your credential:
   - **Outline** – Exam content outline & competencies
   - **Guide** – Candidate Guide with policies, sample items, and study tips
   - **Case Study** – Scenario-based practice
   - **Preview** – Short preview quiz
   - **Practice Exam** – Practice test with scoring

Before you register

- Read your Candidate Guide and Testing Guide (remote proctoring rules, ID requirements, system check, reschedule/cancel windows).
- Confirm your name on the account **matches your government ID.**
- Run the **system check** on the device and network you will use on test day.

Need help?

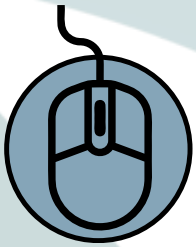
See FAQs or Contact Us from the Study Guides page.

FEES

All fees are non-refundable

Examination Fees

- The total exam fee is $395 (=$50 Application + $345 Examination).
- The $50 application fee is non-refundable.
- If you are found ineligible, CPS refunds the $345 examination portion automatically.
- After you schedule an appointment, reschedule/cancel windows and fees apply (see Administrative Policies, pp. 9–11).
- Payments are online only by Visa, Mastercard, or American Express (U.S. dollars).
- If paid by a third party (e.g., employer), any permitted refund is issued to that payer.
- Applications are not accepted by mail, phone, or fax.



$395

TOTAL EXAM FEE

Application + Examination
Includes a **non-refundable $50 application fee**.

Note: If an applicant is determined ineligible, CPS refunds the $345 examination portion. The $50 application fee is non-refundable.

Group Fee Payments

CPS will accept group payments for certification exams from institutions. Details are on the CPS website.

Other Non-refundable Payment Related Fees

Incomplete Application Fee >
All incomplete applications are subject to a non-refundable $30 reprocessing fee upon the submission of proper documentation. See page 9 for more information.

License Verification >
If licensure information is requested requiring an additional submission, the candidate will have two weeks to provide the license with all the correct information and pay the non-refundable $30 reprocessing fee. If this is not provided within the two weeks, the application will be marked ineligible. Ineligible applicants will receive a refund minus the $50.00 non-refundable application fee. There are no refunds or withdrawals for applications using a bulk code.

Credit Card Chargeback >
Assessed only if a credit-card dispute is resolved in CPS's favor. Future registrations may be blocked until balances are cleared.

FEES

All fees are non-refundable

Computer exam candidates can change their scheduled testing date to a **$50 non-refundable fee**.

Candidates may do this from within their CPS account.

Refer to CPS Testing Guide for details.

Other Exam Related Fees

Reschedule (date/time) — $50 >

Allowed ≥ **48 hours** before your appointment via your CPS account. Changes inside 48 hours are not permitted; the **no-show** policy applies.

Exam Change — $125 >

Administrative change to switch to a different exam (before an appointment is scheduled). May require re-review of eligibility.

Withdrawal — $165 >

Cancel your exam before scheduling or ≥ 7 days before your appointment to withdraw. CPS refunds the examination portion ($345) minus $165. Within 7 days, or after a no-show, the examination portion is forfeited. See Administrative Policies (pp. 9–11) for full timelines.

Retest — $395 >

Retest candidates must pay the full application ($50) and examination ($345) fees and must observe a 45-day wait before reapplying.
See Retest Policy (p. 9).

Refunds

Ineligible Computer Testing Applicants will receive a refund of the $345 examination portion (the **$50 application fee is non-refundable**) minus any outstanding charges.

No refunds

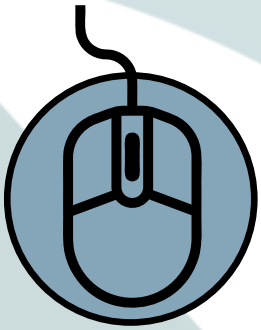
will be issued for the following circumstances:

- Candidates who are not successful in achieving certification.
- No-shows or candidates who fail to test.
- Candidates who are unable to schedule within the eligibility period and do not withdraw per policy.
- Once an exam session has started.

COUNCIL ON PHARMACY STANDARDS

CANDIDATE HANDBOOK

STEPS TO REGISTER



HOW TO REGISTER FOR A CPS EXAM (REMOTE, COMPUTER-BASED)

STEP 1

Confirm eligibility

Review the **Eligibility Criteria** for your credential (link to section).

STEP 2

Submit your application

Submit your application online at the CPS website **PharmacyStandards.org**. Applications can only be submitted online. You cannot submit an application by mail, telephone or fax. Payment must be made online by credit card. Individual or group payments can be made.

STEP 3

Prepare your documents

To get prepared to complete the application - *see the application checklist on the next page*. It is a handy listing of all the information you will need to supply.

STEP 4

Email confirmation of your registration

After completing and submitting the application, you will receive an email confirmation within 30 minutes. **This will be the ONLY confirmation notice you will receive for your application. If you do not receive it, please make sure the email in your profile is accurate and check your email folders.**

STEP 5

Application approval procedure

The application will be reviewed to determine qualification to take the examination. This process can take up to two weeks, depending on the volume of applications received at the time of submission. If the application is incomplete, *see page 10* to learn how to resubmit the application and what fees will need to be paid.

STEP 6

Notification of eligibility to take the exam

If approved, an Eligibility Letter will be emailed and posted in your CPS account with instructions to schedule your exam.

Before scheduling:

- Run the system check on the device/network you will use.
- If you need accommodations, submit your request before booking.
- Ensure your account name matches your government ID.

Eligibility period: You must schedule and test within your 365-day eligibility period (see your letter).

CPS is not responsible for lost or misdirected email. ***Please make sure the email in your profile is accurate and check your account 5-7 days after you have registered*** to ensure your application was complete and additional information is not needed. If you do not receive your examination eligibility letter within 2 weeks of your examination application submission confirmation, use the "Contact Us"link on **PharmacyStandards.org** and select "Application I already submitted" from the drop down menu, to inform CPS.

APPLICATION CHECK LIST

Before filing your application look over the below checklist and gather the information needed to complete it.

☐ **PERSONAL INFORMATION:**

You have complete contact details (name as it appears on your government ID, address, phone, email). Your CPS profile email is current and monitored.

☐ **ELIGIBILITY:**

You reviewed the eligibility requirements and meet one pathway (Standard or Certificate/Training)

☐ **LICENSURE:**

You have your pharmacist license or primary-source verification showing name, license number, jurisdiction, type, and expiration date ready to upload. If not in English, include a certified English translation. Non-US grads include FPGEC® Certification (as applicable). Your license name matches your government ID or you have legal name-change proof.

☐ **EMPLOYMENT:**

You know your current employer contact info (address, phone, email) and have 5-year work history (titles, dates, specialty area, supervisor/contact). Include gaps/unemployment where applicable.

☐ **SPECIALTY QUALIFICATION DOCUMENTS:**

You have documentation for your pathway:

- Standard: summary of qualifying duties and estimated 2,000 hours/12 months within the stated window (verifiable).
- Certificate/Training: certificate of completion (or PGY/residency/fellowship/degree) plus syllabus/competency summary.

☐ **APPLICATION AGREEMENT:**

You will check the agreement box to e-sign the statements below. Applications cannot be submitted without consent.

I have read and agree to abide by CPS policies in the Candidate Guide and Testing Guide, including fees, reschedule/withdrawal timelines, and conduct rules. I understand and consent to remote proctoring, including room scan, screen share, and audio/video recording for security and audit. I certify the information provided is true and complete; I understand that false or misleading statements may result in denial, invalidation, or revocation. I understand my application is subject to audit and authorize CPS to contact employers, licensing boards, and education providers to verify information. I acknowledge the $50 application fee is non-refundable and that other refunds are governed by the published policy.

ADMINISTRATIVE POLICIES

Incomplete Application Processing

An application is **incomplete** if any of the following apply:

- Missing or incorrect information.
- Licensure proof missing required data (name, license number, jurisdiction, type, expiration date) or is not in English without a certified translation.
- Payment not authorized or reversed (declined card, return, or chargeback).
- Any issue that prevents CPS from determining eligibility.

Process:

Incomplete applications are returned with instructions to upload the missing items and pay a **non-refundable $30 reprocessing fee**. All filing deadlines continue to apply. If the resubmission does not fully resolve deficiencies, the application is declared ineligible (the **$50 application fee is not refundable**).

Retest Policy

Candidates who wish to retake a CPS exam must submit a **new application**, meet the then-current eligibility criteria, and pay the **full application ($50) and examination ($345) fees**. CPS does not limit lifetime attempts, but the maximum number of attempts in a calendar year is **three (3)**. Each retest uses a different form of the exam.

Mandatory waiting period

- A **45-day wait is required from the date/time of the last attempt before submitting a retest application or scheduling a new appointment.**
- The wait applies to all delivery modes of testing and all exam forms.
- Applications submitted before the 45-day mark are **not accepted**. If submitted in error, the **application fee remains non-refundable**.

Interruption / invalid attempt rules

- If an exam session experiences **candidate-side** failure (device, internet, environment, refusal of proctoring/ID), the attempt is **invalid** and a retest after 45 days is required; fees follow the **No-Refunds** policy.
- If CPS or the test vendor causes the outage, CPS will provide a no-cost reschedule of the same attempt (no 45-day wait) or, if the attempt cannot be restored, a retest after 45 days without additional fees beyond the original exam fee.

Result notice

- The 45-day date is shown on the candidate's **results/attempt notice** and in the CPS account.

All timelines and fees are governed by the most current online policy at pharmacystandards.org; online versions supersede print.

All policies and procedures are subject to change without notice

CANDIDATE HANDBOOK

ADMINISTRATIVE POLICIES

Changes & Withdrawals

Reschedule (date/time) — $50 non-refundable

For the same exam, you may change your appointment ≥ 48 hours before the start time via your CPS account.

- Must remain within your 365-day eligibility period.
- Limit: 1 reschedule per registration (additional changes require a withdrawal + new registration).
- No changes allowed < 48 hours before the appointment or on exam day.
- See Fees for no-show rules.

Exam or Eligibility-Window Change — $125 non-refundable

Use this to switch to a different CPS exam or to adjust your eligibility period (no appointment scheduled yet).

- Re-establish eligibility for the new exam; CPS may request additional documentation.
- Any approved change uses the original 365-day period (no reset).
- Request must be submitted ≥ 30 days before the end of your eligibility period.
- Limit: 1 exam/window change per registration.
- No refunds of original fees or the change fee.

Rescheduling (same exam): $50 | Exam change: $125

All candidates requesting a change MUST:

- Submit the change request within one calendar year from the first date of their original assigned eligibility period.
- Cancel their exam date (if they have one scheduled), before submitting a change. Scheduled exams may also be canceled using the "Schedule" link in your account.
- Use the CPS website online Change Request Form.
- Submit a non-refundable fee of $125 with the Change Request Form.

Not permitted

- Changes on exam day or after the appointment start time.
- Switching exams after check-in begins.
- Only CPS pharmacy credentials may be selected.

To change examination category:

- Eligibility must be re-established for the new exam category, and additional documentation and fees may be required.
- The time to consider eligibility for the new category will count toward the original assigned computer testing window.
- ***Examinees must take the exam for which they have been determined eligible. No changes will be permitted on examination day***. If a candidate knowingly or unknowingly takes an examination other than they were found eligible to take, the examination will not be scored. No refunds will be allowed, and all fee policies will apply if the candidate reapplies for an examination.
- Candidates must submit their request at least 30 days prior to the end of their 365-day eligibility period.

ADMINISTRATIVE POLICIES

Withdrawal Policy - Computer Testing

- Only the applicant/candidate may request a withdrawal.
- When you may withdraw:
  - Before scheduling an appointment, or
  - ≥ 7 days before your scheduled appointment time (withdrawal cancels the appointment).
- Refund: CPS refunds the examination portion ($345) minus a $165 withdrawal fee → $180. The $50 application fee is not refundable. Any outstanding charges are deducted from the refund.
- Requests < 7 days before the appointment or after a no-show are not eligible for any refund.

Withdrawal Policy - Bulk Purchase Voucher

Withdrawals are not allowed after eligibility is determined. Refunds are governed by the bulk purchase agreement; CPS does not issue refunds for redeemed codes. (Institutions manage reassignment within their terms.)

Substitution Policy

Candidate substitutions are not allowed. The name on the registration must match the government ID presented on test day. Name changes require legal documentation before scheduling.

Score Cancellation

CPS may cancel scores and/or invalidate an attempt for irregularities (e.g., identity mismatch, prohibited items, coaching, tampering, exam content disclosure, policy violations) with or without proof of intent. Fees are not refunded. CPS may impose waiting periods or bar future testing per policy.

Auditing Applications

Applications are subject to audit. Candidates must provide requested documentation (e.g., licensure, employment verification, training certificates) within 14 days. Failure to respond or verify may result in denial or revocation. By submitting an application, you authorize CPS to contact employers, licensing boards, and education providers for verification.

All policies and procedures are subject to change without notice

GENERAL POLICIES

How Exams are Scored

CPS exams are **criterion-referenced**: your outcome is compared to a predefined performance standard, **not** to other candidates. The passing standard is set through periodic **standard-setting studies** (e.g., Angoff/Bookmark) conducted with subject-matter experts and approved by the CPS Board.

CPS uses **item response theory (IRT)** and **test equating** to place different forms of the exam on a common scale. Because some forms may be slightly harder or easier, equating ensures fairness—candidates meeting the standard on any form receive the **same pass/fail decision**.

Score reports provide:

- Your **overall result** (Pass/Fail).
- **Content-area diagnostics** to guide study. These diagnostics are **not percent correct** and are **not comparable** across candidates or attempts. Labels indicate performance **relative to the standard** (e.g., **Below Target / Near Target / At Target / Above Target**).

The passing standard may be reviewed periodically to reflect current practice and blueprint updates.

Retention of Computer Answer Strings

CPS retains computer answer strings and operational testing data for a minimum of 3 years and may retain longer for quality assurance and legal/regulatory purposes. Identity verification media (e.g., audio/video from remote proctoring) are retained per the CPS Privacy & Data Retention Policy.

Test Disclosure

CPS does not release live test questions, answer keys, or full forms. Using, sharing, soliciting, or possessing exam content—before or after testing—is a security violation and may result in score invalidation, revocation, and suspension of testing privileges.

All policies and procedures are subject to change without notice

GENERAL POLICIES

ADA and Nondiscrimination Policies

CPS does not discriminate on the basis of **age, sex, pregnancy, race, color, religion, national origin, ethnicity, disability, marital status, sexual orientation, gender identity or expression, military/veteran status, or genetic information**.
Testing accommodations. CPS provides **reasonable accommodations** consistent with the Americans with Disabilities Act (ADA) for qualified candidates. Requests must be **submitted with the application and before scheduling** an appointment, using the CPS Accommodation Request Form (see **pharmacystandards.org/accommodations**). Documentation must be **current** and signed by a qualified clinician describing the functional limitations and recommended accommodations. CPS will acknowledge requests within **5 business days** and issue a determination within **15 business days** of receiving complete documentation. Information is **confidential** and used only for accommodation determinations. Denials may be **appealed** per the Appeals Procedure below.

Appeals Procedure

Candidates may appeal eligibility determinations, accommodation decisions, exam administration irregularities, or policy applications. Appeals must be **submitted in writing within 60 days** of the decision or event and should include relevant facts and supporting documents. CPS will acknowledge receipt within **5 business days** and render a written decision within **30 days** (or notify if additional time is required). Appeals are reviewed by the **CPS Policy Review Committee**, independent of the original decision maker, and may be escalated to the **Board of Directors**.
CPS does **not** release exam content or answer keys; score verification involves **administrative/technical re-scoring only**.

Revocation

Certification may be denied, suspended, or revoked for: falsification or misrepresentation; **exam security violations** (cheating, proxy testing, item disclosure); misuse of CPS names, logos, or marks; failure to meet or maintain eligibility/recertification requirements; **loss or restriction of the license to practice pharmacy**; nonpayment of required fees; or other material policy violations.
Prior to action, CPS will provide **written notice** of the allegations and an opportunity to **respond**. A written decision (which may include sanctions and eligibility to reapply after a specified period) will be issued and may be **appealed** under this policy.

Designation Authorization

Certification is a non-transferable, revocable, limited, non-exclusive license to use the certification designation, subject to compliance with the policies and procedures, as may be revised from time to time.

Any use or display of CPS certification marks and/or logos without the prior written permission of the CPS is prohibited. Any candidate or certificant who manufacturers, modifies, reproduces, distributes or uses a fraudulent or otherwise unauthorized CPS certificate, CPS designation or other credential may be subject to disciplinary action, including denial or revocation of eligibility or certification. Any individual who engages in such behavior also may be subject to legal action.

All policies and procedures are subject to change without notice

GENERAL POLICIES

Renew Your Certification

CPS requires **recertification every three (3) years** to verify ongoing competence in each credential's core knowledge areas.

Recertification Steps

Earn the required credit using either:

1. Continuing Education (CE) that fits your topics, or
2. Approved professional activities (e.g., teaching, publications, precepting, quality-improvement/projects, committee work).
3. Finish within 3 years, upload documentation, and keep records for audit.

Lapse & Reinstatement

If requirements are **not met by the deadline**, the credential **expires**. Expired credentials may be regained only through **re-examination**, subject to the then-current eligibility criteria. CE completed **after** expiration cannot be applied retroactively.

Audits & Recordkeeping

CPS randomly audits recertification applications. If selected, you must provide CE certificates and short activity descriptions within the requested timeframe. Maintain CE documentation **throughout the cycle and until approval**.

For further details, visit the CPS website **PharmacyStandards.org** and download the recertification catalog for a full description of the recertification process. Click on **Renew your Certification** on the home page.

Verification of Your Credential

CPS provides **third-party verification** of active credentials on request.

- **When available:** After official results post to your CPS account and your digital certificate is issued.
- **What is verified:** Credential name and ID (if applicable), **status** (active/expired), **original certification date**, and **current expiration date**.
- **How to request:** From the CPS website (see **pharmacystandards.org/verification**), select **Request a Verification**, enter the recipient's email, and submit payment.
- **Fee & delivery: $30 per request.** Verifications are sent by email to the designated party.
- **Notes:** CPS cannot verify until certification is achieved. Ensure your name and profile information are accurate before submitting a request.

All policies and procedures are subject to change without notice

EXAM CONTENT OUTLINE

How to Study

CPS does not provide review courses or study materials for the examination. CPS views the examinations as an evaluative process. Eligibility criteria have been established to identify minimum levels of preparation for the examinations. CPS believes your practice experience is your best preparation. Candidates can review detailed test outlines and suggested resources in the Candidate Guides.

Domain 1: Regulatory Compliance and Study Start-Up (25%)

Task 1: Implement global and federal regulations for clinical research.

Apply the principles of ICH GCP E6(R3), including risk-proportionate approaches and quality-by-design.

Interpret and apply FDA regulations (e.g., 21 CFR Parts 11, 50, 56, 312) governing human subjects and electronic records.

Differentiate the regulatory responsibilities of the sponsor, investigator, and Institutional Review Board (IRB).

Manage trial registration and results reporting on public registries (e.g., ClinicalTrials.gov, CTIS).

Task 2: Evaluate clinical trial protocols for feasibility and safety.

Analyze the medication-related sections of a draft protocol for clinical and operational feasibility.

Assess the complexity of the protocol's medication preparation, dispensing, and administration requirements.

Evaluate the adequacy of institutional resources to safely conduct the trial.

Provide expert feedback to the principal investigator and study sponsor on the protocol's pharmacy manual.

Task 3: Manage IRB and other regulatory submissions.

Manage pharmacy-related documents for IRB submissions, including initial reviews, amendments, and continuing reviews.

Ensure the informed consent form (ICF) accurately describes all medication-related procedures and risks.

Manage the Investigational New Drug (IND) application process for investigator-initiated trials.

Report unanticipated problems involving risks to subjects or others to the IRB and sponsor.

Task 4: Manage site initiation and activation procedures.

Lead the feasibility assessment and budget development for the pharmacy components of a new trial.

Participate in site qualification and initiation visits to represent the pharmacy's capabilities.

Develop and implement study-specific pharmacy standard operating procedures (SOPs).

Ensure all required contracts and agreements are in place before study activation.

Task 5: Design study-specific pharmacy procedures and tools.

Translate protocol requirements into detailed, step-by-step procedures for IP handling.

Create study-specific order sets and medication records within the electronic health record (EHR).

Develop comprehensive worksheets for the preparation and dispensing of the investigational product.

Develop clear instructions for nurses on the proper administration of the IP.

Task 6: Implement a risk-based monitoring (RBM) plan.

Contribute to the development of a risk-based monitoring plan for the trial.

Identify high-risk pharmacy processes that require more intensive monitoring.

Utilize remote monitoring platforms and centralized data review to oversee trial conduct.

Implement quality-by-design (QbD) principles in IDS operations.

EXAM CONTENT OUTLINE

Domain 2: Investigational Product (IP) Management and Logistics (30%)

Task 1: Manage IP procurement, receipt, and inventory.

Oversee the ordering, receipt, and quarantine of all investigational products.

Implement and manage a robust temperature monitoring program, including documentation of excursions using validated digital systems.

Manage the IP resupply process to ensure an adequate supply is always on hand.

Ensure compliance with all import/export regulations for international trials.

Task 2: Manage the preparation of sterile and non-sterile IPs.

Apply USP <797>, <795>, and <800> standards to the compounding of IPs.

Implement a robust quality assurance process, including independent double-checks, for all compounded IPs.

Manage the preparation of placebos and comparator agents.

Ensure the stability and appropriate beyond-use dating of all prepared IPs.

Task 3: Manage advanced therapy investigational products (ATIMPs).

Implement handling procedures for cell and gene therapies, biologics, and other advanced modalities.

Manage unique storage requirements, such as cryopreservation, and chain of identity.

Oversee complex preparation processes, including thawing and bedside verification.

Ensure compliance with FACT-JACIE standards where applicable.

Task 4: Manage IP dispensing, randomization, and blinding.

Utilize Interactive Response Technology (IRT) systems to manage randomization and drug assignment.

Implement and maintain rigorous procedures to protect the study blind at all times.

Develop and follow a formal procedure for emergency unblinding when medically necessary.

Label all IPs with the required information according to regulatory standards.

Task 5: Manage IP accountability, reconciliation, and disposition.

Maintain complete, accurate, and contemporaneous drug accountability records for each protocol.

Perform regular reconciliations of the physical inventory against the accountability records.

Investigate and resolve any discrepancies in a timely and documented manner.

Manage the return or destruction of all used and unused IP at study close-out.

Task 6: Implement IP logistics for decentralized clinical trials (DCTs).

Design protocols for direct-to-participant shipping and home delivery of IP.

Ensure cold chain integrity is maintained during transport and at remote storage locations.

Utilize technology for remote monitoring of IP storage conditions and participant adherence.

Manage IP accountability in a decentralized trial environment.

Domain 3: Clinical Trial Conduct and Participant Safety (20%)

Task 1: Evaluate medication-related eligibility criteria.

Analyze a potential participant's medication history against the protocol's inclusion/exclusion criteria.

Identify any prohibited concomitant medications or contraindications that would exclude a participant.

Communicate medication-related eligibility concerns to the principal investigator and research coordinator.

EXAM CONTENT OUTLINE

Assess the participant's ability to adhere to the study medication regimen.

Task 2: Implement the informed consent process.

Explain the medication-related aspects of a clinical trial to potential participants.

Answer any questions a participant may have about the investigational product, its risks, and its alternatives.

Verify that the participant has provided voluntary, informed consent before any study procedures begin.

Manage the eConsent process in virtual or decentralized trials.

Task 3: Manage participant education and adherence.

Provide detailed counseling on the proper use, storage, and administration of the investigational product.

Educate the participant on the use of any study-specific digital health tools (e.g., ePRO, wearables, adherence apps).

Implement strategies to monitor and promote participant adherence to the IP regimen.

Use the teach-back method to confirm the participant's understanding of key information.

Task 4: Manage a participant's concomitant medications.

Perform a thorough medication reconciliation at each study visit.

Identify and manage any potential drug-drug interactions between the IP and concomitant medications.

Provide guidance to the participant and their other providers on which medications are permitted by the protocol.

Document all concomitant medications accurately in the source records.

Task 5: Evaluate and manage adverse events and toxicities.

Recognize, assess, and grade adverse events (AEs) and serious adverse events (SAEs).

Assess the causality of an adverse event to determine its relationship to the investigational product.

Collaborate with the sponsor's pharmacovigilance team to ensure timely and accurate safety reporting.

Implement protocol-specified dose modifications or supportive care to manage toxicities.

Task 6: Implement strategies to enhance diversity and inclusion.

Contribute to the development of recruitment and retention strategies for underrepresented populations.

Ensure that participant-facing materials are culturally competent and available in appropriate languages.

Address potential barriers to trial participation related to social determinants of health.

Ensure compliance with FDA and NIH guidelines on diversity in clinical trials.

Domain 4: Documentation, Audits, and Financial Management (20%)

Task 1: Manage study documentation and data integrity.

Maintain a complete and organized pharmacy file for each clinical trial, including the electronic Trial Master File (eTMF).

Ensure that all source documents are compliant with ALCOA-C principles.

Enter and manage pharmacy-related data in clinical trial technology systems (e.g., EDC, CTMS).

Respond to data queries from the study sponsor or data management team in a timely manner.

Task 2: Manage monitoring visits, audits, and inspections.

Prepare all pharmacy documentation in advance of a monitoring visit, audit, or inspection.

Host monitors, auditors, and regulatory inspectors and facilitate their review of pharmacy records.

Develop and implement a formal corrective and preventive action (CAPA) plan in response to audit findings.

Foster a culture of audit readiness and continuous quality control.

EXAM CONTENT OUTLINE

Task 3: Manage data and safety monitoring activities.

Prepare and provide data on drug exposure, dosing, and adverse events for safety reviews.

Contribute to the preparation of reports for the Data and Safety Monitoring Board (DSMB).

Manage the reconciliation and reporting of serious adverse events (SAEs) to the sponsor and IRB.

Analyze dispensing and accountability data to ensure the integrity of the trial.

Task 4: Manage research billing compliance.

Differentiate between medications and services billable to the study sponsor versus the participant's insurance.

Contribute to the development of a Medicare Coverage Analysis (MCA) for all study-related items and services.

Ensure that investigational products are not billed to the participant or their insurer.

Collaborate with the research billing and finance departments to prevent billing errors.

Task 5: Manage financial performance of the Investigational Drug Service (IDS).

Develop a standardized fee schedule for IDS services.

Negotiate the pharmacy budget with the study sponsor during study start-up.

Track all billable events and manage sponsor invoicing and milestone tracking.

Conduct periodic reviews to ensure the IDS is financially sustainable and recovering costs.

Task 6: Manage expanded access programs.

Differentiate between various types of expanded access programs (e.g., single patient IND, intermediate-size).

Manage the receipt, storage, and accountability of compassionate use investigational products.

Collaborate with the clinical team and IRB to ensure all regulatory requirements are met.

Ensure proper billing and cost recovery for expanded access treatments.

Domain 5: Leadership, Education, and Innovation (5%)

Task 1: Evaluate and implement new technologies.

Assess new technologies for their potential to improve the safety and efficiency of IDS operations.

Lead the implementation and validation of new software and automation.

Develop training programs for staff on new technologies.

Stay current with innovations in pharmacy research technology.

Task 2: Implement training and professional development programs.

Serve as a preceptor for pharmacy students and residents on IDS rotations.

Provide ongoing education to pharmacy staff on clinical research principles and regulations.

Educate nurses, physicians, and research coordinators on medication-related aspects of clinical trials.

Present on investigational drug services at institutional or professional meetings.

Task 3: Implement quality improvement initiatives.

Lead or participate in quality improvement projects to enhance the safety and efficiency of the IDS.

Develop and monitor key performance indicators (KPIs) for IDS operations.

Use quality improvement methodologies (e.g., PDSA, Lean) to drive process improvements.

Foster a culture of continuous quality improvement within the IDS team.

Task 4: Manage interprofessional teams and relationships.

Serve as the primary liaison between the IDS and the broader research community (e.g., investigators, coordinators).

EXAM CONTENT OUTLINE

Lead multidisciplinary teams including pharmacy, nursing, and regulatory personnel on research initiatives.

Participate in institutional research oversight committees.

Advocate for the role of the pharmacist in the clinical research enterprise.

Task 5: Document and manage IDS policies and procedures.

Develop and maintain a comprehensive set of standard operating procedures (SOPs) for the IDS.

Establish a process for the periodic review and updating of all SOPs.

Ensure that all IDS practices are consistent with the written SOPs.

Maintain all SOPs in a controlled and readily accessible format.

Task 6: Contribute to the advancement of research pharmacy practice.

Participate in professional organizations related to research pharmacy.

Contribute to the medical literature through scholarly activity, such as publications or presentations.

Mentor junior staff and trainees interested in a career in research pharmacy.

Develop innovative solutions to common challenges in investigational drug management.

ABOUT CPS

The Council on Pharmacy Standards (CPS) develops and administers professional certification programs for pharmacists. CPS awards credentials to qualified candidates who meet eligibility requirements and successfully pass the appropriate examination. Our programs validate advanced competence in contemporary practice areas, helping candidates demonstrate specialized expertise and employers verify it.

CPS certifications span pharmacy law and compliance, sterile and non-sterile compounding, immunization and public health, point-of-care testing, medication safety and quality, controlled substances stewardship, pharmacogenomics, telepharmacy, veterinary compounding, specialty pharmacy, and pharmacy informatics.

CPS PHILOSOPHY OF CERTIFICATION

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