Session Title	Test Questions
Clinical Trial Supply Boot Camp	1. What incident drove the Federal Food, Drug and Cosmetic Act of 1938? a. The publishing of The Jungle, by Upton Sinclair b. The elixir of sulfanilamide tragedy c. The thalidomide tragedy d. None of the above 2. The following are all Quality System Elements except: a. Training Program (Quality Unit and other functions) b. Specifications (Component and Product) c. Quality Agreement in place d. Component Vendor Qualification Program e. External Due Diligence Inspections 3. Our responsibility for tracking clinical supply conditions and storage ends when it arrives at the clinical site. a. True b. False 4. How long should a stability study supporting clinical supplies continue? a. The scheduled stability study timeline b. At least 6 months beyond the end of the clinical trial c. At least the duration of the clinical trial d. All of the above e. None of the above 5. Which of the following statements about the EU Clinical Trial Regulation (CTR) is CORRECT? a. The greatest challenge of the new CTR is that each Trial Master File will have to be archived for 25 years. b. A sponsor must file 2 clinical trial applications in every member state. c. The CTR requires the expiry date to be printed on labels

The Basics of Forecasting & Planning Boot Camp	1. Investing in software to forecast clinical trial supply needs can benefit a company in which way? a. The software is completely automated enabling the organization to eliminate personnel b. Material requirements determined by predictive software's are absolute therefore stock out risk is eliminated c. Using software to determine a minimum amount of expensive comparator required can significantly impact savings on procurement of clinical trial material d. Material requirement calculations established by predictive software are inherently more accurate than any other method 2. Information required to create a study forecast includes all of the following except: a. List of Participating Countries b. Number of Patients c. Patient Birthdates d. Dosing Duration 3. Failure to accurately determine a study's material needs can cause which of the following issues: a. Depot stock out situations b. Missed Patient Visits c. Large amounts of IMP waste d. all of the above 4. Establishing a maintaining a robust supply plan requires maintaining a communication flow with which of the following groups: a. Clinical Project Manager b. All Site PIs c. Marketing Department d. both b and c
Interactive Response Technology (IRT) Boot Camp	1. Where should the control of an IRT system reside? a. Clinical Operations b. Quality Assurance c. Clinical Supply Unit d. Only at the IRT vendor e. None of the above 2. The following are all IRT System stages except: a. User Requirement Specification (URS) Development b. IRT build c. Validation d. User Acceptance Testing (UAT) e. Quality Technical Agreement (QTA) 3. What's the usual timeline to build an IRT? a. 2-3 weeks b. 6-8 weeks c. 12-14 weeks 4. When's the best time to consider building in the module for Returns and Reconciliation? a. Half way through the study b. At least 2 months before the end of the clinical trial c. At the beginning of the clinical trial d. All of the above e. None of the above

Developments in Expanded Access	1. Which of the following is correct? a. Continued Access is the new name for what used to be called Compassionate Use b. The term Expanded Access is a broad description that encompasses a variety of ways that patients can obtain access to life-saving medication in emergency need c. US, EU, and Japan regulations governing Expanded Access programs have recently been harmonized by ICH committee d. It is beneficial for companies to initiate EA programs because it is a way to obtain data that can be used in filings not covered under the IND 2. One way an Expanded Access (EA) program differs from a traditional clinical trial (CT) program is: a. Because of emergency need, any EA program is automatically accepted globally while CT programs require individual review and approval b. Per regulations, the FDA is bypassed for EA programs conducted in the US but is heavily involved in CT programs c. The FDA must be contacted for an EA program however there is an expedited approval process d. CT programs are part of the development of a novel compound that may include commercial drugs as comparators. EA programs involve only commercial drugs. 3. Which of the following is an aspect to be considered when establishing an EA program? a. EA programs impact a variety of functions within an organization so a cross-functional team should be involved in establishing the program b. On-time drug delivery is the primary concern so the CT supplies organization should be in control of any EA program c. Approval of an EA request requires rapid review so the EA program should be established with a single person responsible for all aspects of the program in order to reduce decision time d. Social media and public pressure are dictating that all companies create EA programs regardless of actual need
Cell Gene Therapy Supply Chain	1. The supply chain for cell gene therapy needs to consider which of the following: a. Temperature control. b. Material procurement. c. Cost. d. Direct to patient delivery. e. All of the above. 2. Which of the following is not considered a component of an optimized cold chain? a. Real-time or near real-time data collection and transmission. b. Using pressuring cells in GMP grade solution. c. Comprehensive environmental data monitoring. d. An under-qualified shipping container. e. Surveilling logistics. 3. What are the benefits to cell therapy of an optimized cold chain? a. Maintains cell viability. b. Improves cell recovery. c. Improves cell return to function. d. Improves clinical outcomes. e. All of the above.

Aligning Clinical Supplies Documentation with Trial Master File Expectations	1. When using an eTMF: a. Additional metadata are needed at the system and artifact level b. Digital documents in their original format could be included c. Users can digitally sign documents d. All of the above 2. Requirements for the Investigational Product in the eTMF include: a. Randomization and unblinding Procedures b. Informed Consent of trial subjects c. Safety Reporting d. Premature termination or suspension of trial documentation 3. Which of the following can be done to prepare for an Inspection: a. Print out all relevant pages from the eTMF b. Ensure compliance with protocol, SOPs, GCPs and or applicable regulatory requirements c. Organization of eTMF into one (1) of the fourteen (14) model zones d. Ensuring that there is no linkage between the eTMF and the common technical document (CTD)
Culture of Accountability (2 hour session)	1. Some ways to assess your level of accountability in your team are to measure the amount of people that demonstrate: a. Always considering all options and creating an action plan b. Consistently create and achieve SMART goals c. Act on plans immediately and consistently d. All of the above 2. Ways to improve accountability within your team are: a. Invite feedback b. Do a thinking styles assessment c. Only hire people with Emotional Intelligence d. None of the above 3. The most important way to improve accountability on your team is to: a. Remove the fear factor b. Provide stretch opportunities c. Give coaching and feedback d. Reward mistakes with humiliation 4. A classic example of building accountability into your team can be found in: a. The PSA system at the Virginia Mason Institute b. General Electric's Vitality Curve c. Toyota's Andon Cord System d. NASA's Quality System checks on Manufacturing the solid rocket boosters on The Challenger

BREXIT's Impact on Distribution	1. In the event of Hard Brexit, the EU sites will: a. Be able to receive shipments from US, UK or EU depots b. Ship from anywhere as a QP release is no longer required c. Must receive only supplies that are released by an EU resident QP. d. All of the above 2. Identify which of the following is an appropriate risk mitigation strategy to ensure patient continuity in the EU post Brexit. a. Ensure supplies released by a UK QP are moved into the EU prior to Brexit to allow for their continued use by EU sites. b. Set up a relationship with an EU QP to ensure ongoing release of supplies. c. Notify regulatory that no udpates are required to CTA's if a new EU releasing site is added for EU QP release d. Only a & b e. Only b & c 3. Clinical supplies for use by the EU-27 may be packed: a. In the EU only b. In Western Europe only c. Any site that is listed in your CTA filing for that protocol, as long as EU QP release is performed prior to use in the EU-27 d. At select sites in China and India only
Brexit: Impact to Pharmaceutical Regulations	1. Which of the following are potential impacts to clinical trials? a. UK QP Release. b. Importation Restrictions. c. Regulatory Submission. d. All of the above. 2. What is BREXIT? a. British Regional Extinguisher Convention. b. Alignment as the 51st state. c. British Exit from the EU. d. A new treaty between the UK and US. 3. What activities should be considered in BREXIT analysis? a. Value Added Tax (VAT). b. Changes to label text. c. Increased number of clinical trial applications. d. Both a & b. e. Both a & c.

Pharmaceutical Industry in the 22nd Century: Journey into the Future	1. How has Cell and Gene therapy impacted the Clinical Supply Chain and how we support them? a. Better understand the origin of the product to identify autologous versus allogeneic sources. b. Be prepared to transport product at cryo temps (-150 to -180C). c. Identify ways to speed up the clinical supply delivery timeline. d. All of the above. 2. The definition of IOT utilized in this presentation is: a. Index-Organized Table b. Internet of Things c. Interoperability Testing d. Initial Operating Target 3. What's the best way to describe how block chain can be used for the clinical supply chain? a. A shareable distribution overview available to anyone that has access to the internet b. An overview supply chain protocol that cannot be hacked and gives access to the latest supply chain data c. A system that can be set up to provide access to only specific people or all people depending on what is needed d. All of the above. e. None of the above.
Quality Agreements	1. Identify the necessary parts of a good quality agreement: a. Who and how deviations and Out of Spec (OOS) will be handled b. Who will handle inspections, testing and release c. Who and how complaints will be handled d. How audits and inspections will be done and how often e. All of the above 2. The reason a quality agreement is not required in the US is: a. The FDA doesn't see the value in quality agreements. b. The FDA hopes most US companies will follow the EMA's standards. c. The FDA believes a quality agreement is absolutely necessary, but legislation has not been finalized and approved yet. d. The FDA relies on the Code of Federal Regulations to identify what should go into Quality Agreements. e. None of the above. 3. The best way to clarify roles and responsibilities is to use a RACI chart. The A in RACI stands for: a. Agile b. Adaptable c. Accountable d. Allocation e. None of the above

EU Regulation 536/2014 (Clinical Trial Regulation) and the Regulatory Impact on Clinical Supplies.	1. Which is a difference between an EU Regulation and Directive: a. There is no difference. b. Directives require all member states to create regulations that will comply with the directive c. A directive stipulates what must be enacted but not how d. A regulation requires strict compliance by all member states e. b, c and d 2. When will EU Regulation 536/2014 become effective in practice? a. Dec 31, 2017 b. After the EU Portal and EU Database requirements have been implemented c. Once greater than 50% of member states have ratified it d. All of the above 3. The Clinical Trial Regulation is being implemented because: a. It was time for a change b. The Clinical Trial Directive allowed too much room for interpretation into regulations c. The EMA was aware of all clinical trials being conducted in Europe d. The EMA wanted to create more jobs
Artificial Intelligence in Clinical Supplies	1. AI is also known as: a. Metadata analysis b. Machine learning c. Infinite "if-then" loops d. Pay to play e. None of the above 2. To implement AI on drug development, all of the following departments will need to be involved except: a. Clinical operations b. Biostatistics c. Clinical Supplies d. IT e. Analytical development 3. The current drug development paradigm in the industry today will be "disrupted" by AI within the next: a. 1-2 years b. 3-5 years c. 5-10 years d. 10-20 years e. Never

Challenges of Developing a Clinical Supply Chain in Asia Pac	1. Describe concerns with reverse logistics of clinical supplies from the various countries in Asia Pacific. a. There are no concerns b. You only have to worry about it at the end of the study. c. Start your discussions about reverse logistics, returns and destruction in Asia Pacific prior to the start of your study. Ensure your vendor / s have a plan, and that your contracts account for the various possibilities as they pertain to reverse logistics. 2. Effectively describe (on a basic level) issues with returns and destruction of clinical supplies from the following countries as well as awareness of import requirements and license types for general import and export of clinical supplies. Pick the one that is NOT true. a. Japan, South Korea, and Taiwan don't have strict rules. Anyone can manage destruction of materials and it doesn't matter what methods of destruction are used. b. Singapore can be used as an Import for re-export hub. In that you can import in, export out, and return through Singapore for returns and destruction c. There is a land bridge between Singapore and Malaysia 3. Describe considerations for language requirements in countries where English is not a primary language. Pick the best answer. a. Only English is needed because it is the global language for business. b. Ensure that all label text translations are reviewed by your local in country office or your CRO. With this ensure that either your local internal partner or CRO vendor approve the text. There are nuances linguistically in each country that make this critical for success. Additionally ensure that all manuals, site instructions, and other operational needs/directives always have a local language translations for partners and vendors to reference. Consider a translator for critical discussions and or a vendor with local language resource. c. Only the local language is required and no English text on label is allowed.
Ancillary supplies - Partnering with CROs	1. Some risks associated with sourcing ancillary supplies can be avoided by doing which of the following? a. Always split the outsourcing of comparators and ancillary supplies between competing CMOs. b. Maintain a safety stock supply of low cost, commonly used items. c. Establish a process that enables clinical sites to always supply ancillary items locally so they can obtain exactly what they need when they need it. d. Supply US clinical sites from a central warehouse and give local companies in other countries the ability to supply locally sourced ancillary items. 2. A good trigger for starting a supply strategy for ancillary materials is: a. At the same time the study drug supply plan is initiated. b. Within 1 month of sourcing any comparators since both will be purchased materials. c. Anytime, the CRO doesn't need lead time. d. 3 to 6 months before the start of the initial packaging supply depending on the kit design. 3. When creating an ancillary supplies strategy for a global clinical trial, what factors should be considered? a. Customs import requirements in each country. b. Labeling requirements in each country. c. Distribution times to supply sites in each country. d. The CROs licenses and capabilities in each country. e. All of the above.

Vendor Management	1. Which of the following are advantages of outsourcing aspects of packaging and labeling of clinical trial supplies? a. Responsibility for the quality of the final product is removed from the innovator company b. The scale of the work required can be highly adjustable to meet demand c. Provides a wide range of choices as all companies offer the same services d. It's always cheaper to outsource whatever you can 2. Which of the following must be considered when outsourcing IMP production activities? a. Facilities being used are included in country regulatory filings b. The facility performing the activities has been audited to allow QA & QP release of the material c. Proper planning, scheduling, and timelines d. All of the above should be considered when outsourcing IMP production activities 3. What are the two most common types of IMP supply chain outsourcing models used? (select two): a. Specific partnership/project provider b. Strategic partnership/preferred provider c. Favorite Service Provider d. Functional Service Provider e. a and b f. b and d
Best Practices for Adaptive Trials	1. Adaptive Trial Design is: a. Unplanned changes to protocols based on interim study data b. Randomly timed changes to ensure blinding in the study. c. Prospectively planned modifications to one or more aspects of the design based on accumulated patient data. d. Changes based on data from a competitors protocol results e. All of the above 2. Which of the following situations might help the Clinical Supply Chain respond quickly to supply needs in adaptive trials? awaiting until the revised protocol is fully signed off prior to planning & executing necessary packaging jobs. b. Utilize a Just-in Time labeling strategy to keep supplies flexible c. Label supplies without any Protocol or sponsor related information on them d. All of the above 3. Which of the following it NOT true concerning Adaptive Trial Design? a. ATD always uses the same supplies throughout the trial with no changes b. Usually considered as an afterthought after the trial has begun c. Only allows changes if there is a question of efficacy of the drug d. Both a & b e. None of the above

CMC Regulatory Workshop (Filings and how they relate to IP)	1. Which of the following is required to be included in an US IND? a. Justification for the expiry dating that will be applied to the study drug. b. The approximate time that will be required to manufacture the drug substance. c. The HTSUS code that will be applied when importing each drug into the US d. The company and location where the study drug will be stored and distributed. 2. Which functional areas are responsible for providing information to be included in the CMC section of an IND? a. Regulatory is responsible for all of the information as the function completing the filing process with the FDA. b. The clinical supplies function is responsible because the filing will be used to enable a clinical trial. c. Representatives of the various functions within the CMC team are individually responsible for information. d. The Line management of the representatives of the various functions within the CMC team. 3. How can the CMC information in an application impact study drug supply? a. Modifications made to the drug substance manufacturing process can limit the countries where the study drug can be used. b. The stability protocol will be used to establish future extensions to the expiry date for the study drug. c. The list of locations where packaging will occur can limit the supply chain options. d. All of the above
Direct to Patient	1. How does a direct-to-patient (DtP) model benefit patients? a. The patient does not have to make numerous trips to the investigator site. b. Patients can be more in charge of their schedule in relation to the trial. c. Temperature control issues are reduced. d. Both a & b. e. a, b & c. 2. The challenges and subsequent risks with a DtP model are: a. Varying country regulations and GxP polices. b. Deliveries can be left on the front porch. c. Temperature integrity throughout transport & delivery. d. Both a & c . e. None of the above are challenges. 3.Which of the following is NOT true: Central Pharmacies support DtP model by: a. Managing patient information so the sponsor has no access to it b. Managing the storage of material in a GMP compliant manner c. Shipping materials to the patients current location d. They add complexity for the patient.

Managing Importation Requirements for Your Products	1. Which of the following are ways to ensure compliance with import/ export regulations for clinical trial supplies? a. Ship materials the same way you send your letters b. Contract with a broker / courier that offers these services. C. Use your internal or a Full Service Distribution vendor's customs compliance/ import export group with expertise in clinical supply movements d. Both a & b e. Both b & c f. All of the above 2. The sponsor company can delegate which of the following responsibilities: a. Importer of Record b. Exporter of Record c. Brokerage / Clearance in destination country d. It depends on the shipping & receiving countries and the legal status of all involved companies in those countries. 3. The sponsor that delegates some of their importation responsibilities to a 3rd party, has what accountability in the event of a customs/ revenue audit? a. No accountability, it is delegated to the 3rd party. b. Ultimate accountability, although they may rely on the 3rd party for support & documentation required to submit to the audit c. Accountability can not be delegated within AFME countries d. Sponsor is not accountable for these activities so there is no need to delegate.
Import and Export of Controlled Substances	1. Which statement below is true for distribution of controlled study drugs a. The requirements for import & export of controlled study medication has been harmonized across the US, EU, and Asia. b. Planning the distribution of controlled drugs has been simplified by the establishment of the Universal Drug List that all countries use to established which drugs are to be controlled. c. The US documentation requirements differ depending on the classification of the scheduled drug. d. EU regulations place restrictions on the same controlled substances as the US but do not cover drug precursors. 2. What 2 key documents are mandatory in the US to enable movement of CII study drug to or from US sites? a. DEA 41 and DEA 82 b. DEA 222 and DEA 222a c. DEA 222 and DEA 223 d. DEA 224 and DEA 225 3. What aspect below about import/export of controlled substances is correct? a. US requirements for importing controlled substances are strict but there are no requirements for export so it is simpler to manufacture within the US. b. Anyone wishing to conduct a trial using a CII drug must register the drug within 30 days of importing it or must forfeit all drug to the Agency. c. If the amount of controlled substance being imported is greater than the amount registered on the permit the difference is seized by the Agency and only the permitted amount is allowed to be imported. d. Registration with the DEA must be made before the importation of any controlled substance is allowed.

Temperature Data at the Clinical Site - The Missing Piece of the Puzzle	1. A temperature excursion is defined as: a. When an IMP is exposed to a temperature above 30°C b. When an IMP is exposed to a temperature below -20°C c. When an IMP is exposed to temperatures outside the label storage conditions d. Both a and b 2. When evaluating a temperature excursion event which functional areas should be involved in dispositioning the material: a. Line Management b. Analytical Sciences/Stability c. Clinical Operations d. Site Study Manager 3. Ways to reduce temperature excursion dispositioning time include: a. Collecting temperature cycling stability data to establish allowable excursion information b. Pre-approving temperature excursion documents c. Allowing the site to disposition the material directly d. Not requiring second person verification to complete disposition
Insource or Outsource cGMP Batch Documentation	1. When responsibility for batch record review and product release are outsourced to a contract vendor, who is responsible for cGMP? a. The owner / innovator of the product b. The contract vendor c. Neither a nor b d. Both a and b 2. Responsibilities for cGMP activities such as batch record review can be shared between owners and contract facilities as long as: a. The parties document the expectations in a an email b. The activities of each of the parties for all CGMP-related roles and manufacturing operations are clearly defined c. They agree who is to blame when something goes wrong d. All of the above 3. When managed appropriately, outsourcing or co-owning batch record review can: a. enhance speed and efficiency b. provide technological expertise c. expand capacity d. b & c e. a, b & c

How to Develop SOP's to Meet Regulatory Expectations	1. Who is the best person to be the author an SOP? a. The manager of the impacted unit b. A representative from the Quality Assurance unit c. A consultant d. An operator experienced with the process 2. A thoroughly written SOP should contain which of the following elements? a. No fewer than 20 pages of text to ensure the process is thoroughly documented. b. A list of all areas impacted by the SOP. c. Humorous text so that the readers will better remember the content. d. Space in the margins for readers to make comments and corrections. 3. What factors are used to determine when SOPs be established? a. The number of employees in the company using the process. b. The phase of the trials being conducted that the process impacts. c. The need to clarify responsibilities across the process. d. Notification of a pending inspection.
Maintaining a Patient-First Perspective in Your Clinical Supply Chain	1. All of the following are examples of attributes booklet labels should incorporate to enhance patient compliance EXCEPT for: a. Omit subject friendly instructions and include only the minimally required regulatory language on the label b. Include an index to enable subjects to locate their language quickly. c. Keep the font size as large as possible d. All of the above are examples of label attributes that would enhance patient compliance 2. Which of the following packaging/labeling techniques could be used to enhance patient compliance? a. Blister cards for complex dosing regimens b. Different colored labels to distinguish between daily dosing times c. MEMS caps d. All of the above 3. A subject’s negative experience with self-administering their IMP could: a. Impact the statistical outcome of the study b. Discourage their involvement in future studies c. Result in an over or under reporting of adverse events d. All of the above

How to Partner with Your Clinical Sites, a Shared Perspective from a Site Pharmacist and CMO	1. The following are issues experienced by clinical sites when receiving their clinical supplies for a trial: a. Print on the labels font size is so small it's almost unreadable b. Identification numbers on clinical supplies are needlessly long and all of them start with 000 c. Clinical supplies are delivered on a weekend when the site is closed d. Clinical supplies are delivered with a temperature deviation and can't be used e. All of the above 2. The best way(s) to eliminate clinical supplies issues at the site is: a. Consider the challenges the site experiences every day b. Send larger shippers to provide extra storage to the folks at the site c. Talk to as many different clinical site representatives and integrate their recommendations into your clinical supplies packaging, labeling and shipping d. All of the above e. Only a and c 3. When shipping clinical supplies to a clinical site implementing the following will usually provide the best outcomes: a. Have your own temperature recorders in all temperature controlled clinical supply storage areas b. Provide a notification to the site via e-mail, text and call before a clinical supplies shipment arrives at the site c. Providing training to the sites on what the shippers will look like and how to receive the shipments and store them at the right temperature d. Provide a shipping notification via fax using 4 point font after the package has been received e. b and c
Best in Class Temperature Controlled Distribution	1. Which of the following is the best way to ensure you minimize the risk of a temperature excursion during shipment when you have minimal stability data? a. Include a data logger in the shipment b. Add extra ice packs to your water based shipper to fill in any empty space c. Use a qualified shipper packed out according to instructions d. Both a and c 2. Which of the following will NOT help minimize temperature excursions? a. Providing clear instructions and training to sites on how to handle the arrival of IP shipments in order to minimize time out of storage b. Working with a vendor/ courier to determine the most suitable transportation method and shipping solution for the product c. Assuming all personnel handling the product understand it’s stability profile and that no instruction is needed d. Providing labels on and instructions in the IMP shipments to help direct any handlers on appropriate storage/ shipping conditions 3. Which of the following statements is true? a. Shipments made with active temperature-control shippers will always clear customs faster than passive shippers. b. All passive shipper types should be avoided because they are single-use and therefore more expensive than active shippers. c. Passive shippers are more commonly used than active shippers. d. Active temperature-controlling shippers should be the first choice for any shipment because they come with a guarantee from the manufacturer that the contents will be maintained at the correct temperature throughout transport.

Enrollment Accuracy & Forecasting	1. All of the following are true for enrollment accuracy EXCEPT: a. An IRT is required b. The IRT should include clinical supply requirements to schedule shipments c. Enrollment reports should be provided on a daily basis d. Enrollment will directly impact forecasting 2. Forecasting systems do the following: a. Integrate enrollment data into the supply chain plan b. Provide an alert when enrollment is above or below forecast c. Allow a sponsor company to utilize new strategies to improve enrollment d. All of the above e. None of the above 3. Some options available in today's forecasting technology include: a. Integrating real-time enrollment data from the IRT b. Predictive technology to identify which sites should receive critical supplies c. Retinal scanning for passwords d. Facial recognition e. a and b
The Future of Automated Systems for Clinical Supplies	1. Which of the following parts of the clinical supply chain could most benefit from new technology? a. Planning and Forecasting b. Labeling c. Packaging d. Cryogenic Storage and Distribution e. a, b and c 2. Which of the following could greatly improve the latest clinical supply chain technology? a. RFID b. Batteries with an exponentially longer use life c. A standardized two-dimensional barcode d. Temperature monitors that can record down to -180C e. b, c and d 3. Which of the following impacts technology rollouts to the pharma/biotech industry? a. The industry's risk averse nature b. IT departments' resistance to change c. Poor change management programs linked to technology adoption d. All of the above e. None of the above

Measuring Return on Investment (ROI) in Forecasting Clinical Supplies	1. In order to create an accurate forecast which of the following factors should be included? a. number of randomization strata and participating countries b. drug dating period and manufacturing plan c. treatment groups and dosing plan d. all of the above 2. Which statement is true about forecasting options? a. An integrated commercial system will always produce more accurate results over manual calculations. b. The method used to establish a forecast should be proportional to the complexity of the trial to be supplied. c. The method used to establish a forecast should be as automated and integrated as the company's budget will allow. d. A draft forecast should be created using a spreadsheet before using an automated system. 3. What advantage does an automated system have over manual forecasting methods? a. Provides a consistent forecasting structure for every trial b. Greater flexibility to provide re-evaluations when study parameters change c. Lower cost to implement d. Ability to interface with other systems to incorporate actual study data for adjustments e. Answers a, b, and d
Strategies for Using Pooled Supplies	1. Which of the following labeling strategies support product pooling? a. Multiple protocols printed on the label b. Using a program-level ID c. Ancillary label added at the point of distribution d. All of the above 2. Which of the following is generally NOT a reason to pool supplies? a. Product supply is limited b. Multiple studies with the same drug product will be conducted at the same sites c. Product is plentiful and inexpensive d. Product is extremely expensive such that traditional overages are economically unfeasible 3. Which of the following are factors that contribute to the success of IP pooling for a global study? a. Due diligence to determine if your country list will support a pooled supply strategy and developing a 'back-up' strategy in case a country does refuse b. A written rationale for IP pooling that can be provided with the CTA at time of submission, or can be used to support country questions post-submission. c. Work with an IWRS vendor that has proven experience with managing pooled inventory across protocols. d. All of the above

Planning Returns & Reconciliation in a Global Trial Following Regulations in Latin America	1. Since regulations change, options for remaining compliant with the current regulations include: a. Contracting with a local company to provide updates. b. Obtaining updates from an affiliate in that country. c. Subscribing to updates available at agency websites. d. Any of the above 2. Which of the following is NOT a best practice for drug reconciliation, returns, and destruction? a. Automate repetitive, manual tasks. b. Define the detailed reconciliation plan when the study is nearing completion. c. Provide effective training for all involved stakeholders. d. Clearly define the roles and responsibilities. 3. Which of the following are advantages of local destruction? a. Challenges of exporting expired or unused material is avoided. b. Minimize costs of moving material to another facility to be destroyed. c. Able to take advantage of site destruction capabilities. d. All of the above
Autologous Therapy Supply Chain Strategies	1. Which of these best describes Autologous sourced cells? a. Cells from another individual b. Cells from the same individual c. Cells that have been created by an automated process d. None of the above 2. Cell & Gene Therapy distribution strategies require: a. Fast turn-around b. Planning and Forecasting c. Cryogenic shipments d. None of the above e. All of the above 3. Which of the following is true? a. Cell & Gene therapy could be the wave of the future b. Autologous cells are always preferred over Allogeneic cells c. Cell & Gene Therapy has been the cause of patient mortality d. a and c

IRT Systems Development and Standards	1. Where should the control of an IRT system reside? a. Clinical Operations b. Quality Assurance c. Clinical Supply Unit d. Only at the IRT vendor e. Both a and c 2. The following are all IRT System stages except: a. User Requirement Specification (URS) Development b. IRT build c. Validation d. User Acceptance Testing (UAT) e. Quality Technical Agreement (QTA) 3. When's the best time to consider building in the module for Returns and Reconciliation? a. Half way through the study b. At least 2 months before the end of the clinical trial c. At the beginning of the clinical trial d. All of the above e. None of the above
Embedding a CRO Within a Sponsor	1. Which of the following should be put into place before implementing an embedded vendor in a sponsor company? a. A very good incentive program for the vendor's employees b. Clearly defined roles and responsibilities c. Gap assessment of the current relationship between Clinical Supplies and Clinical Operations d. Ensuring the right ergonomic office furniture is available e. b and c 2. Approximately how much time should be allocated to clearly identifying the roles and responsibilities of the embedded vendor employees? a. A day b. A week c. A month d. An amount determined by the Gap Assessment of the current unit versus the embedded vendor employees 3. Which of the following is true? a. Success will be determined by accurately assessing requirements before contacting the vendor for embedding an employee b. Successful implementation will occur by moving as rapidly as possible c. Embedding vendor employees should be limited to distribution functions d. Embedded vendor employees should have a limited contract time

Comparator Sourcing Strategies	1. When determining a sourcing strategy for a comparator product, what factors should be considered? a. Blinding capability of the comparator product b. Availability of required strengths of the comparator are available in all required countries c. A comparator's availability in all targeted countries for the Clinical Trial d. b and c 2. Which of the following are NOT an advantage of local sourcing? a. Can avoid sharing trial information b. Shorter timelines to procure c. Could involve multiple suppliers d. None of them are advantages 3. In which of the following scenarios should you use Central Sourcing? a. Taste studies b. Early Phase I trials c. Phase III studies d. Both a & c e. All of the above