

CE	#	Session Title	Session Description	Learning Objectives
Y	Seminar 1	Understanding the Essentials of the Clinical Supply Chain	This class is geared toward people new to the clinical trial supplies world, and focuses on drug development and what goes into planning for and delivering a study drug for clinical trial. Topics include: reasons behind Good Manufacturing Practices (cGMPs), phases of new drug development and approval, randomizing and blinding clinical trial materials, quality assurance and documentation, protocol interpretation, patient compliance, labeling, standard operating procedures, stability, Good Distribution Practices (GDPs), returned drug accountability, and changing regulations in the EU and ROW. Attendees will hear a massive amount of information in a fun and interactive atmosphere.	<ul style="list-style-type: none"> (1) Describe at least three (3) historical events that drove the development of Good Manufacturing Practices (GMPs) (2) Identify at least three (3) quality rules to ensure investigational medicinal product (IMP) production meets global regulatory standards (3) List three (3) regulatory requirements when shipping temperature-controlled Investigational Medicinal Products (IMPs)
Y	Seminar 2	Cell & Gene Therapies: Essentials of Cell Gene Therapy Supply Chains	Cell & Gene therapies are increasing at an impressive rate. It is important to understand the manufacturing processes and supply chain requirements of these life-saving therapies. This boot camp will describe and contrast the different manufacturing and supply chain requirements of autologous and allogeneic cell and gene therapies.	<ul style="list-style-type: none"> (1) Compare and contrast the supply chain requirements of Autologous and Allogeneic therapies (2) List no fewer than three (3) key requirements that both Autologous and Allogeneic therapies must have to ensure successful distribution and dosing (3) Diagram how Autologous and Allogeneic Cell platforms must be organized to integrate into the clinical supply chain (4) Differentiate how Cell & Gene therapy supply chain requirements differ from non-Cell & Gene therapy supply chain requirements
Y	Seminar 3	Exploring Direct to Patient Clinical Trial Models	Expanding access to patient populations, faster recruitment, increasing patient retention and decreasing time to market are all reasons sponsors are exploring Direct-to-Patient (DtP) clinical trial models. This bootcamp is designed to discuss best practices to engage your clinical teams, clinical sites, and couriers to ensure a successful partnership in a DtP supply chain model.	<ul style="list-style-type: none"> (1) Describe at least two (2) benefits of the Direct-to-Patient supply chain model for clinical sites, sponsors and patients (2) Identify at least two (2) risks for sponsors conducting Direct-to-Patient trials and effective mitigation strategies (3) List no fewer than three (3) study characteristics to consider when making the decision to use a Direct-to-Patient strategy (4) Describe no fewer than three (3) requirements when coordinating a Direct-to-Patient delivery linked to a visiting nurse arrival
N	Seminar 4	Expanded Access Platform Seminar	This interactive seminar will give an overview of expanded access and discuss new regulations and their impact on the planning and execution of Expanded Access Programs.	<ul style="list-style-type: none"> (1) Distinguish between 'Continued Access' and 'Expanded Access' (2) Identify three (3) challenges associated with supplying an Expanded Access request (3) Name two (2) types of Expanded Access scenarios and distinguish the difference(s) between their classifications
Y	Seminar 5	Importing and Exporting Clinical Supplies	The class is designed for clinical supplies professional that want to learn more about shipping and distribution for global clinical trials. This seminar will cover regulations, temperature control, customs challenges, and logistics supply chain partnerships to ensure success with international distribution	<ul style="list-style-type: none"> (1) Identify four roles necessary for completing an international shipment and the responsibilities of each of the roles (2) Identify at least 3 documents needed to be maintained for recordkeeping and explain why they must be kept. (3) Name the global association that has responsibility for writing customs valuations guidance
Y	Seminar 6	Interactive Response Technology (IRT) in Clinical Supply Chain Seminar	This class is geared towards people that have some experience in the clinical trial supplies world. Attendees will be provided with a quick overview and then will take a deeper dive into Interactive Response Technology (IRT). This will include the development path for IRTs; the stages of build, from creating the User Requirement Specification (URS) to quoting, coding, validation, user acceptance testing and go-live; the reasons to use an IRT as well as when NOT to use an IRT; build requirements, including randomization codes and med code IDs; ensuring modules are built to manage individual regulatory country approvals, shipping requests and returns and reconciliation; as well as timelines from concept development to system go-live.	<ul style="list-style-type: none"> (1) Identify how IRT integrates into the Clinical Supply Plan (2) Define the required timelines and stakeholders for successful setup and operation of an IRT system (3) Explain the challenges of User Acceptance Testing (UAT) and IRT validation (4) Summarize the required content, details and potential pitfalls to implementing an IRT system
N	CO	Conference Orientation	This informal 1/2 hour discussion will provide you with an overview of the conference, use of the conference app and tips on how to get the most out of everything while you're here.	N/A

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N	KN	Keynote	Great teams that sustain in the long run are built on the successful foundation of great cultures. It is the culture that reinforces the purpose and values as the team grows and expands. By focusing on individual and shared purpose, and fostering an environment of trust which leads to authenticity, then can you build a culture that promotes life-transforming collaboration. Travis Thomas is the author of "3 Words for Getting Unstuck: Live, Yes And!"	N/A
N	PT1	Patient Testimonial	Tom and Kari Whitehead founded The Emily Whitehead Foundation in honor of their daughter Emily. A leukemia survivor, Emily was the first child in the world to receive CAR T-cell therapy. They have seen first hand how cancer research is saving lives! Come hear about the Whitehead Family's journey over the past 10 years.	N/A
N	PT2	Patient Testimonial	Ann is an advocate for adolescents to be included in adult clinical trial. She is a mom of 4 children, 2 who have Li-Fraumeni Syndrome, a genetic condition which predisposes them to all forms of cancer. She has quite a story that dates back to 2004 when her daughter, Lauren, was diagnosed with adrenal cancer at the age of 17 months. Her son, Brent, was diagnosed with Osteosarcoma in 2011 at the age of 11. Come to hear the Ramer Family's journey and ongoing battle with cancer & research.	N/A
N	P1	Making the Most of your GCSG Membership	There is so much going on at GCSG beyond our annual conference! This session will update you on the benefits of membership and updates we've made to better serve YOU, our members.	N/A
Y	P2	What Can We Learn from the Military Supply Chain	The agility, adaptability and execution that the military brings to the supply chain has numerous transferable concepts to the clinical supply chain. Both exist in a VUCA (Volatility, Uncertainty, Complexity and Ambiguity) environment. This session will examine which concepts from the military supply chain, capable of going anywhere in the world in 48 hours, can be utilized in the clinical supply chain.	<p>(1) Compare and contrast military supply chain strategies versus clinical supply chain strategies</p> <p>(2) Identify no fewer than two (2) key concepts the military employs that can be utilized in the clinical supply chain</p> <p>(3) Explain the top three (3) factors go into making the military supply chain strategy as effective as it is and how they can be implemented in the clinical supply chain</p>
Y	P3	The Changing European Regulatory Environment	Clinical supply chains are adjusting to recent changes in the regulations. This workshop will provide an opportunity to discuss the recent changes and ask questions of a QP from the EU.	<p>(1) Compare and contrast how the requirements for CT Supplies in EU Regulation 536/2014 differ from those in Directive 2001/20/EC</p> <p>(2) Identify when EU Regulation 536/2014 became effective by law and when it will become effective in practice</p> <p>(3) Explain no fewer than two (2) reasons the Clinical Trial Regulation is being implemented</p>
N	PNET1	Licensed Pharmacist Networking	Get together with fellow pharmacists to discuss how pharmacists can share knowledge and expertise to help colleagues in the clinical supply industry.	N/A
Y	MP1	Challenges of the Cell, Gene, CAR-T and Personalized Medicine Supply Chains	Over the course of the last decade, there has been an increased emphasis on research and development into personalized medicines including cell, gene and immunotherapy treatments. Due in part to advancements in science and the availability of more sophisticated diagnostic tools, which give the medical community a better understanding of the human genome and make it easier to detect genetic mutations affecting individual patients, the outlook is positive. Come to this workshop to learn more about the challenges of cell, gene, CAR-T and personalized medicine supply chains.	<p>(1) List two (2) major strategies employed for delivering a robust personalized medicine supply chain</p> <p>(2) List at least two (2) concerns in the handling of cell and gene therapy clinical materials</p> <p>(3) Describe a potential labeling solution appropriate to the labeling of cell and gene therapy products</p>
Y	MP2	Understanding Blockchain and AI in the Clinical Supply Chain	Blockchain is a type of distributed ledger, an expanding chronologically ordered list of cryptographically signed, irrevocable transactional records shared by all participants in a network. AI (Artificial Intelligence) or ML (Machine Learning) refers to software technologies that make a robot or computer act and think like a human. This presentation will explain what Blockchain and AI are and discuss how they are transitioning from theoretical concepts to how they are being implemented into the Clinical Supply Chain.	<p>(1) Describe what Blockchain is and how it can help the clinical supply chain</p> <p>(2) Explain what must be done with the clinical supply chain now in order for us to get the most out of AI</p> <p>(3) Give examples of how AI and Blockchain can be used to accelerate the clinical supply chain</p>

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Y	MP3	The Clinical Trial Regulation and its Evolving Regulatory Impact on Europe & ROW	Clinical supply chains are adjusting to recent changes in the regulations. This workshop will provide an opportunity to discuss the recent changes and ask questions of a QP from the EU	<ul style="list-style-type: none"> (1) Compare and contrast how the requirements for CT Supplies in EU Regulation 536/2014 differ from those in Directive 2001/20/EC (2) Identify when EU Regulation 536/2014 became effective by law and when it will become effective in practice (3) Explain no fewer than two (2) reasons the Clinical Trial Regulation is being implemented
Y	MP4	Brexit Update: Impact on the Clinical Supply Chain	The session will give you an understanding of how the United Kingdom's exit from the European Union has affected the clinical trial supply chain. Experiences will be shared regarding challenges in the implementation of new processes post BREXIT.	<ul style="list-style-type: none"> (1) Provide a definition of BREXIT and the impact on clinical supply change (2) Identify next steps in the BREXIT process (3) Identify two (2) key ways that BREXIT has impacted clinical trials
N	MP5	Impact of Falsified Medicines	The Falsified Medicine's Directive became effective in the EU February 2019. The aim of the directive is to prevent counterfeit medicines from entering the supply chain although it has a wide range of impacts from manufacturing through distribution. This min-presentation will present details of how this directive will impact the clinical supply chain and steps that should be taken to ensure compliance.	N/A
N	MP6	Pathways for Patient Access to Investigational Drugs	This class provides a broad overview of the different mechanisms to support patients ability to access investigational drugs. Each mechanism has different requirements, which will be covered in this course, enabling you to successfully understand which is the best pathway based on the patient need. Topics covered will include Expanded Access, Right To Try (RTT), Continued Access, Clinical Trials and Patient Assistance.	<ul style="list-style-type: none"> (1) Learn the multiple pathways available to patients to access investigational drugs (2) Understand the difference between regulation vs company policy and how they relate. (3) Identify the appropriate pathway based on 'real' patient scenarios
Y	MP7	Challenges of Developing a Clinical Supply Chain in Asia Pac	Developing and maintaining a robust clinical supply chain in Asia Pac doesn't have to be challenging. Planning up front for your Asia Pac distribution and import/ export strategy can greatly increase your chances of success within the region. This workshop will discuss best practices for storage, distribution, import/ export and reverse logistics in South Korea, Thailand, Malaysia, Singapore, China, New Zealand and Philippines. You will also get some hands on experience by working through a scenario for an Asia Pac study!	<ul style="list-style-type: none"> (1) Describe three (3) concerns with reverse logistics of clinical supplies from the various countries in Asia Pacific. (2) Identify the minimum requirements and license types for import/export of clinical supplies as well as issues with returns and destruction of clinical supplies from the Asia Pac countries (3) Discuss language requirement considerations in countries where English is not a primary language.
Y	WS01	Approaches for Forecasting Clinical Trials with Limited Data	When forecasting clinical trial supply needs we bring as much data to the table as possible in order to better understand inventory requirements, overages, campaigns and the overall supply chain. What happens when our data is limited and it impacts the value or quality of the forecast? This workshop will discuss ways to get the best forecast when data is scarce.	<ul style="list-style-type: none"> (1) Summarize what to do when clinical trial data is minimal but forecasts must be generated to decrease waste (2) List two (2) ways that forecasts can be generated at the beginning of a trial when limited data is available (3) Compare the value of forecasting when data is plentiful versus when it is limited
Y	WS02	Linking Sponsor and Vendor Systems	As the clinical supply industry continues to outsource more and more operational support, we find that systems integration between sponsor and vendor is essential. This workshop will identify the best ways to link Sponsor companies' internal systems with external vendor systems to create the most efficient clinical supply chain.	<ul style="list-style-type: none"> (1) Summarize the challenges of linking internal sponsor systems with external vendor systems (2) Explain the value that systems integration brings to the clinical supply chain when operations have been outsourced (3) List three (3) key concepts that must be followed to get the best sponsor - vendor system integration
Y	WS03	Understanding Your Responsibilities as Importer of Record (IOR)	Importation and movement of clinical supplies internationally will typically bring up questions about ownership of supplies, importation processes and Importer of Record (IOR) responsibilities. Knowing the specific obligations of the sponsor, clinical research organizations (CRO) and vendors will help to ensure maximum efficiencies when importing. This workshop will clarify the responsibilities surrounding IOR and ownership of clinical trial materials.	<ul style="list-style-type: none"> (1) Summarize the responsibilities of the Importer of Record and why CROs don't want the responsibility (2) Describe when an Importer of Record is needed (3) List three (3) additional responsibilities of the Importer of Record when shipments are made across country borders

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Y	WS04	Developing Strategies for Managing Combination Product (Basket/Umbrella) Studies	Clinical study design is evolving as we work to accommodate flexibility in protocol deliverables and execution. This session will discuss how design has a critical role for adaptive multi-product trials.	<ul style="list-style-type: none"> (1) Define what basket studies are and how they are used in clinical trials (2) Discuss regulatory nuances specific to basket studies (3) Describe at least two (2) options for maintaining supplies for adaptive trials
Y	WS05	Inspection Readiness	Instilling an inspection ready culture in your operations groups is vital to success. Come to this session to bolster your knowledge of how to always be inspection ready!	<ul style="list-style-type: none"> (1) List no fewer than two (2) ways to get team members to consider inspection readiness at all times (2) Describe how to build inspection readiness into clinical supply chain processes (3) Give at least three (3) examples of proper communication techniques during an inspection
Y	WS06	Ensuring Supply Chain Flexibility and Viability for Biologics	Traditionally structured clinical supply chains are inherently inefficient, relying upon large buffer inventories to offset variability in demand. However, by taking a fresh approach and making fundamental changes that allow the supply chain to be more responsive to changes in actual demand, efficiency can be improved. This session will explore the potential of using a demand-led approach to manage clinical supplies, reduce supply chain risk and improve flexibility.	<ul style="list-style-type: none"> (1) Explain the significance of distribution and labeling for clinical supplies (2) Compare and contrast the fundamental differences between push and pull supply chain management as it relates to clinical supplies (3) Describe three (3) differences between JIT Labeling and On Demand Distribution
Y	WS07	Role of the Qualified Person (QP) Post Brexit	The quality and regulatory units and Qualified Persons (QPs) in the EU are adjusting post-BREXIT. This workshop will provide an opportunity to discuss the QP role post-BREXIT as well as give you an opportunity to ask questions and discuss requirements with a QP from the EU.	<ul style="list-style-type: none"> (1) Compare and contrast the QP role pre- & post-BREXIT (2) Identify the date the UK will exit the EU (3) Explain no fewer than two (2) viable options for QP release in a UK-based clinical supply chain
Y	WS08	Distribution Planning and the Role of Depots	As the clinical supply chain expands into more and more countries, distribution planning has become exponentially more complex. This session will delve into the requirements for clinical supply chain distribution planning and where depots and a knowledge of customs requirements are essential	<ul style="list-style-type: none"> (1) Compile a list of at least three (3) countries that require depots (2) Identify at what point during draft protocol development depots should be included in your supply chain distribution planning (3) Determine the requirements of using a 3rd party depot when there is no primary depot available
Y	WS09	Outsourcing Clinical Supply Management	As the incidence of outsourcing the clinical supply chain has increased, understanding the value of clinical supply management using your vendor as a partner has become essential. This workshop will explore how to best utilize your vendor partner as a seamless part of your supply chain.	<ul style="list-style-type: none"> (1) Outline factors that would establish the need for outsourcing clinical supply chain management (2) Describe the capabilities of your vendor's supply chain management function (3) Identify three strategies for maximizing the efficiency of your clinical supply chain when collaborating with your vendor partner
N	WS10	Clinical Supply Horror Stories	Horror stories in clinical supplies...we've all had them! Share your stories and mitigations with your colleagues.	N/A
Y	WS11	Meaningful Metrics (KPIs)	We all know metrics drive performance. The challenge with driving best outcomes for the clinical supply chain is directly linked to the quality of our metrics. This workshop will identify the most meaningful and impactful metrics to track to get the best supply chain performance.	<ul style="list-style-type: none"> (1) Give at least two (2) examples of metrics that can be used to monitor performance in the clinical supply chain (2) Be able to name at least three (3) key attributes that differentiate good KPIs to measurements that do not provide useful information. (3) List at least three (3) ways KPIs/metrics can be communicated to stakeholders
Y	WS12	Adaptive/ Just in Time Manufacturing	The traditional clinical supply chain model has been "Push". The industry is now moving towards a "Pull" model. Just-in-Time (JIT) manufacturing is one key solution for the Pull model. This workshop will explore where we are in adapting and adopting JIT manufacturing.	<ul style="list-style-type: none"> (1) Describe three (3) market drivers changing the clinical supplies market (2) Identify three (3) challenges facing sponsors in an ever-changing clinical supplies market (3) List three (3) ways the JIT manufacturing solution can help overcome these challenges

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Y	WS13	Protocol Interpretation for Clinical Supply Design: A Case Study	Protocol interpretation has become increasingly challenging as protocols have become more complex. This workshop will utilize a case study to demonstrate key processes to utilize to ensure the best protocol interpretation.	<ul style="list-style-type: none"> (1) Explain how and who a misinterpreted protocol impacts. (2) Summarize why protocol interpretation has become particularly complex in oncology and other therapeutic areas (3) Identify at least 3 clinical supply chain requirements from a case study protocol
Y	WS14	Partnering with Clinical Operations Stakeholders	In order to shorten clinical trial timelines and increase efficiency of the clinical supply chain, it is essential to develop an excellent rapport with our Clinical Operations stakeholders. This workshop will explore how to better partner and collaborate with Clinical Operations in order to get the best out of our clinical supply chain	<ul style="list-style-type: none"> (1) Describe the best way to improve your upstream clinical supply chain customer relations (2) Explain how improving the relationship and trust between Clinical Operations and Clinical Supplies can positively impact country selection and the timing of first patient in (3) Give two (2) examples of how good relationships with Clinical Operations has improved Clinical Supplies forecasting and fulfillment
N	WS15	Making the IRT More Site Friendly	Interactive response technologies (IRTs) are used consistently in standard Phase II and III clinical trials. The challenge for Investigator Sponsored Trials (ISTs) is that they typically occur at a single site. This workshop will focus on adapting and orienting your IRT to be more site friendly.	N/A
Y	WS16	Cold Chain Distribution and Temperature Excursions	This workshop will define time out of environment (ToE) and provide a forum for discussing both challenges and solutions for managing labeled storage conditions and ToE. The workshop will address multiple ways the time out of label storage conditions can be minimized during distribution as well as ways to set up a successful temperature management program. Attendees will be able to identify successful strategies for managing temperature excursions when they occur.	<ul style="list-style-type: none"> (1) Define temperature excursion for an Investigational Medicinal Product (IMP) (2) Identify no fewer than two (2) ways to minimize the risk of a temperature excursion (3) Give two (2) examples of ways to proactively and reactively manage temperature excursions in cold chain distribution
Y	WS17	Autologous vs. Allogeneic Supply Chains	As the number of new Cell and Gene therapies grows in the clinical development space, it becomes increasingly important to understand the supply chain challenges of these unique therapies. This workshop will identify and differentiate the challenges of the autologous and allogeneic clinical supply chain requirements	<ul style="list-style-type: none"> (1) Compare and contrast supply chain requirements of autologous versus allogeneic therapies (2) Summarize three (3) key requirements that both autologous and allogeneic therapies must have to ensure successful distribution and dosing (3) Describe how autologous and allogeneic cell platforms must be organized orchestrated to integrate into the clinical supply chain
Y	WS18	Just In Time Labeling and Release - A QP Perspective	Just-in-Time (JIT)/ On Demand supply chains bring quality challenges to the forefront. Come to this workshop to discuss options for releasing IMP in a just-in-time/ on demand supply strategy.	<ul style="list-style-type: none"> (1) Demonstrate three (3) key components of an on demand quality risk based system (2) Identify ways to mitigate quality issues in an on demand clinical supply chain (3) Describe the optimal approach to build quality by design (ICH Q8) into a Just-In-Time system to ensure clinical supply chain control
N	WS19	Use of Pharmacy Manuals in Clinical Trials		N/A
Y	WS20	Returns and Reconciliation	Returns and reconciliation have come under greater scrutiny by regulatory authorities in many different countries. Performing the final reconciliation and disposition of material being returned from a clinical site is typically one of the most challenging aspects of clinical supplies because it requires a better bridge between the GMP and GCP sides of the house. In this workshop options for completing the return process and ways to reconcile the returns will be discussed.	<ul style="list-style-type: none"> (1) List the elements of IMP reconciliation and destruction for clinical supplies (2) Explain how to overcome the challenges of reconciliation regarding site accountability (3) Describe the advantages and disadvantages of local (site/ country) destruction vs centralized destruction

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Y	WS21	Sourcing and Labeling Biologics	Are you working with biologic comparators/ co-meds? Sourcing and labeling biologic clinical trial material presents unique challenges. This workshop will discuss practices used to procure, maintain stock and label biologics.	<ul style="list-style-type: none"> (1) Describe stocking and replenishment models used for biologics in the clinical supply industry and how they are managed (2) Explain how far in advance a biologic sourcing strategy should be considered and why (3) Identify three (3) special considerations for labeling biologic supplies, in particular when using small primary containers
Y	WS22	Improving Patient Adherence	Patient Adherence has long been a concern for conducting successful clinical trials and getting drugs to market. This workshop will explain the difference between adherence, compliance and persistence and ways they can be improved.	<ul style="list-style-type: none"> (1) Explain the impact of poor patient compliance with IMP on clinical studies (2) List at least three (3) examples of technologies that can improve patient compliance (3) Describe the cost-benefits of compliance technologies and how to gain operational support for such initiatives
N	WS23	Program Management	Holistic program management evaluates timing and supply for the entire asset lifecycle in order to synchronize demand and supply across all studies. This in turn drives feasibility/supply plans for all phases of the asset. This workshop will discuss the different aspects involved in overall program management rather than protocol-level project management of clinical supply.	<ul style="list-style-type: none"> (1) Compare and contrast the key difference between protocol level and program level clinical supply management (2) Identify no fewer than two (2) key inputs for program level forecasting (3) Discuss the importance of alignment of supply planning with the overall product development strategy
N	WS24	Cell Therapy Orchestration Platforms	We are all well aware of the extensive work that goes into supplying study drug to a clinical site. However, there are many other activities that happen during a patient's visit to a clinical site in addition to dispensing study drug. This workshop will discuss all of those other activities and the people who performs them as well as ways that CT Supplies organizations can help make the entire patient experience less stressful.	N/A
Y	WS25	Utilizing Operational Excellence to Improve the Clinical Supply Chain	Operational Excellence (OE) is becoming a driver to improve the efficiency when applied to the clinical supply chain. Whether that comes in the form of lean clinical supply chains, better KPIs or automation, it is essential that we implement one, if not more, of these concepts to adapt to ever-changing clinical supply requirements. This workshop will identify the different aspects of Operational Excellence and how they can be used in your clinical supply chain.	<ul style="list-style-type: none"> (1) Describe three (3) of the key elements required to initiate an operational excellence program. (2) Compare and contrast the various tools provided by OE methodologies (Lean, TQM, Six Sigma) and how they can benefit an organization (3) Explain the concept of 'Lean' manufacturing and packaging and how it can be integrated into the clinical supply chain.
N	WS26	Direct to Patient Distribution	Expanding access to patient populations, faster recruitment, increasing patient retention and decreasing time to market are all reasons sponsors are exploring direct-to-patient clinical trial models. This workshop is designed to discuss the safety and quality considerations that should be reviewed when planning a robust direct-to-patient supply chain model.	<ul style="list-style-type: none"> (1) Describe two (2) benefits each for the clinical site, sponsor and patient of a direct-to-patient trial (2) Identify at least two (2) risks for sponsors conducting direct-to-patient trials and develop effective mitigation strategies for these risks (3) Identify two (2) late-stage customization strategies that can support delivery of medication closer to the patient thus minimizing waste
Y	WS27	Pooled Supplies	Supplying multiple clinical trials from a pooled inventory of material provides a number of advantages. This workshop will discuss those advantages as well as options for how pooled supplies can be prepared.	<ul style="list-style-type: none"> (1) Compare and contrast two (2) ways that the preparation of pooled supplies differs from those of protocol-specific labeled supplies (2) Describe three (3) advantages of preparing pooled supplies (3) Summarize the value of bright stock in pooled supplies and the value of influencing Clinical Operations to standardize protocols to utilize brightstock
N	WS28	Change Management	Change is the standard when working within the clinical supply chain. When change must be implemented and adopted, change management becomes essential. The key to change management is not the system being changed, it's the people that must buy into and accept the change to be successful. This workshop will identify ways to ensure people more quickly transition to the new way of working.	N/A

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Y	WS29	Clinical Supply Connections with Clinical Operations and CROs	As the clinical supply chain has become increasingly outsourced, understanding the value of creating better relationships with Clinical Operations and clinical research organizations (CROs) has become imperative. This workshop will describe ways to improve collaboration between clinical supplies and its key partners, Clinical Operations and CROs.	<ul style="list-style-type: none"> (1) Identify why CROs have taken on a more active role in the clinical supply chain (2) Describe how Clinical Operations and CROs are integrated into the clinical supply chain (3) List three (3) ways to improve collaboration and supply chain outcomes when working with Clinical Operations and CROs
N	WS31	Project Management Skills	Everyone in the clinical supply chain uses some sort of project management in their daily jobs. Come to this session to discuss some project management best practices or share some of yours! Whether you are new to clinical supplies or a seasoned professional, there is something for everyone in this workshop!	N/A
Y	WS32	Packaging Temperature-Sensitive Products	As our products become diverse, so do their handling requirements. Many innovative products now must maintain temperature at ultra-low conditions throughout the supply chain. This can present challenges when looking at the 'traditional' pack/label/ ship clinical supply chain. This workshop is designed to discuss challenges and potential solutions when handling, storing, labeling and shipping ultra cold / sensitive materials.	<ul style="list-style-type: none"> (1) Define "Time out of Environment" (2) Identify labeling solutions that avoid compromising product viability for products that must be maintained at ultra-low temperatures (3) Describe no fewer than three (3) potential challenges when storing & shipping materials in liquid nitrogen
Y	WS33	Cold Chain Capabilities and the Rise in Biologics	Biologic development now comprises half of all clinical studies. Understanding temperature controls when developing biologics is essential. This workshop will do a deep dive into temperature control requirements of biologics.	<ul style="list-style-type: none"> (1) Identify key areas of cold chain risk throughout the lifecycle of biologics development (2) List three ways we ensure temperature-controlled during packaging and distribution is successful for biologics (3) Identify aspects to consider when establishing cold chain shipping strategy for biologics
N	WS34	Maximizing Performance with Virtual Workers	The paradigm shift to remote working scenarios can have an effect on communication, productivity, job satisfaction and teamwork. Learn the warning signs of negative impact and ways to optimize performance in this workshop.	N/A
Y	WS35	Strategies for Handling Ancillary Supplies	Ancillary supplies are often the items no one wants to take responsibility for due to their unique procurement and distribution challenges. Over the years they have fallen squarely on the shoulders of clinical supplies folks. This workshop will be a discussion of the various practices used for procuring, stocking, and distributing ancillary items to clinical sites.	<ul style="list-style-type: none"> (1) Describe three (3) stocking and replenishment models used in the clinical supplies industry and how they are managed (2) Describe the procurement timeline for optimal management of ancillary supplies (3) List a minimum of three (3) special considerations for ancillary supplies managed outside the United States