GLOBAL CLINICAL SUPPLIES GROUP


| # | Session Title | Session Description |
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| 1 | **Medical Devices From a Supplier & QP perspective** | This workshop will discuss the ins and outs of medical devices from classification to blinding and everything in between. Share your expertise or come find a mentor to help you navigate the complexity of medical devices. |
| 2 | **Autologous and Allogenic Supply Chains - A Case Study** | This session will cover the differences autologous & allogeneic cell and gene supply chains using a case study. |
| 3 | **Outsourced Clinical Supplies Management Models** | During this session we will share various tips and tricks to getting the best outcomes when managing an outsourced clinical supply chain. |
| 4 | **Maintaining the Cohesion of a Remotely Managed Clinical Supplies Team** | The pandemic showed us the importance of being able to work remotely. This workshop will discuss ways to increase the cohesiveness of a remote clinical supplies team. |
| 5 | **Harmonizing CTM Supply & Demand Plans Throughout the Trial** | The importance of maintaining the harmony across investigational product supply and demand is essential. This workshop will discuss practical and tactical ways to do that. |
| 6 | **How SMART Devices Can Improve Drug Administration** | Drug administration and compliance have always been a challenge. With the advent of SMART device technology, this has become easier. This workshop will discuss how and why to integrate SMART devices into your supply chain. |
| 7 | **Ancillary Supply Management & IRT Integration** | As the use of ancillary supplies grows in clinical trials, using an IRT to manage them has become invaluable. This workshop will discuss how to integrate ancillary supplies into your IRT design implementation. |
| 8 | **Challenges of Importing/Exporting CTM Into & Out of the U.S.** | Many people don't realize how challenging it is to bring clinical supply materials into the U.S. This workshop will discuss the use of the Automated Commercial Environment (ACE) system for import and how to export clinical supplies more smoothly and efficiently. |
| 9 | **Strategies for Programming Resupply Strategies Into Your IRT/RTSM** | This workshop will discuss the factors to consider when determining resupply strategies while using an IRT. While many people think this is something that is programmed into the IRT, it requires well-defined specifications for it to work well. |
| 10 | **Adjusting Operations and Timelines for Critical Projects** | One thing the pandemic has shown us is how well we can handle an increased operational tempo. This workshop will identify the need for timeline and operational flexibility when critical projects are introduced. |
| 11 | **Decentralized Clinical Trial Supply Chains** | This workshop will identify how some companies are using centralized locations to ship medications. The focus will be on how to establish a network of sites & depots that ship within their own network in support of decentralized trials and the pros and cons of doing so. |



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| 12 | **Comparator Sourcing: Best Practices & Innovation in Procurement & Supply Chain** | This workshop will discuss the options for establishing a successful comparator program including acquisition, pedigree, distribution and reconciliation. |
| 13 | **JIT Labeling Success By Collaborating Early With QA** | This workshop will discuss just-in-time (JIT) labeling and how the regulatory landscape has changed to increase QA's support. The focus will be on partnering early with QA to understand and mitigate their concerns in order to get buy-in from the very beginning. |
| 14 | **Project Management Best Practices for Clinical Supplies** | This workshop will focus on defining good project management for clinical supplies and the tools and techniques to ensure projects stay on time and on budget while collaborating with all key stakeholders. |
| 15 | **Operational Excellence in Different Working Structures** | In the chaotic world of clinical supplies, establishing Operational Excellence is invaluable to decreasing the waste of time, manpower and materials while also minimizing errors and rework. This workshop will explain how to implement Operational Excellence as part of the clinical supply chain. |
| 16 | **Decentralized Clinical Trials in APAC, an Emerging Market** | As clinical supply chains expand into Asia-Pac, two areas of opportunity identified during the pandemic were the implementation of decentralized trials (DCTs) and direct-to-patient distribution (DtP). This workshop will identify ways to leverage DCTs while avoiding the pitfalls of working in these emerging markets. |
| 17 | **Clinical Supply Chain Challenges When Working With Emerging Markets in Asia-Pac** | Asia-Pac is a large and diverse array of countries, people, markets and clinical sites. This workshop will identify some of the more common issues and pitfalls with the clinical supply chain and how to overcome them. |
| 18 | **Using Expanded Access: Understanding Supply Chain Requirements, Planning and Forecasting** | This interactive presentation will give an overview of expanded access/compassionate use programs and discuss new regulations and their impact on the planning and execution of Expanded Access Programs. |
| 19 | **Brexit: Lessons Learned & Main Takeaways for the World** | Brexit was finally implemented at the end of 2020. This workshop will discuss the ongoing impacts that it has introduced to the clinical supply chain and how to overcome the challenges of packaging and distributing clinical supplies in the EU-27 and the UK. |
| 20 | **Understanding Site's Challenges with Clinical Supplies** | As patient and site-centricity grow in acceptance and appreciation, understanding the challenges the sites have in working with our clinical supplies becomes critical. This workshop will help you better understand the site's perspective on clinical supplies. |

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| 21 | **Emotional Intelligence & Leadership in Clinical Supplies** | As Millenials & Gen Z's become the majority in our workplaces, it is essential for today's leaders to understand the value of emotional intelligence and new styles of leadership in order to attract, engage and retain this incredible workforce. |
| 22 | **Regulatory, Labeling and Customs Requirements for CTM in LATAM** | Awareness of the regulatory requirements across different agencies is critical for being a successful clinical trial supply professional. This workshop will discuss the regulatory requirements of LATAM countries and how they impact clinical trial supply timelines and planning. |
| 23 | **Taking the Fear Out of Regulatory Audits** | Nothing creates a greater level of gut-wrenching anxiety than being audited by a regulatory agency. This workshop will discuss tips, techniques and best practices to being inspection ready, properly prepared to handle a regulatory audit and able to appropriately interact with inspectors/investigators. |
| 24 | **Blinding Considerations for 2020 & Beyond** | The majority of clinical trials are now on large molecules that are not typical oral solid dosage forms and blinding is an integral part of most of these clinical trials. This workshop will focus on new approaches to blinding these types of clinical materials. |
| 25 | **Blinding Considerations When Utilizing an IRT Configured for Resupply Operations** | If an IRT is improperly configured, you can unblind the site and/or the entire study. This workshop will discuss how to properly design and create specifications to ensure the right people are blinded throughout the study and especially during resupply operations. |
| 26 | **IoR: The Ins & Outs of Global Distribution** | Ever have a shipment going to another country get delayed due to documentation issues? This workshop will discuss what the importer of record (IoR) does, along with various other document requirements that enable shipments between countries to occur smoothly. |
| 27 | **Using Value Stream Mapping to Improve Clinical Supply Chain Efficiency** | Value stream mapping is a lean management method that allows you to visualize, analyze and improve all the steps in a product delivery process. This workshop will focus on how to utilize value stream mapping for the clinical supply chain. |
| 28 | **Lessons Learned From Accelerated Covid Vaccine Development & Approval** | Thanks to the development of the Covid vaccines, it became clear that development times could be compressed while maintaining high quality, rapid scale-up and expedited regulatory approvals. This workshop will identify how standard techniques and processes for vaccines were accelerated and what can be utilized to help with other products in the clinical supply chain. |

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| 29 | **Packaging Technology for Clinical Supplies** | Knowing the best materials and their specifications is invaluable to ensuring stability and compliance. This workshop will explain packaging technology information and requirements to help small companies choose the best clinical supply packaging solutions. |
| 30 | **IMP/CTM Information Required for Regulatory Filings** | The CMC section of the IND contains information that has a direct impact on clinical trial supplies. Failure to prepare IMP that follows the requirements listed in this section can have a significant impact on a clinical trial. This session will discuss the CMC information contained in a clinical trial regulatory filing and how it should be monitored to avoid issues with clinical supplies. |
| 31 | **Metrics - What Are Valuable Metrics to Use for Clinical Supplies?** | As we all know, metrics drive performance. Having the right metrics in place makes all the difference between focusing on the right things or the wrong things. This workshop will identify the best metrics to use to drive the best clinical supply outcomes. |
| 32 | **Risk-Based Management: Tools for the Clinical Supply Chain** | ICH Q9 has been in effect for over a decade, yet most of us don't have an effective risk evalution and mitigation strategy process. This workshop will explore ways to better document and control risk-based management using real life stories and experiences. |
| L1 | **Direct-to-Patient: The Benefits & Why it Should Continue** | This workshop will discuss what we've learned about the value of direct-to-patient (DtP) distribution during the pandemic & why we need to keep it as an option for clinical trials and clinical supplies. |
| L2 | **EU Clinical Trial Regulation (Annex 6) Update** | The Clinical Trial Regulation is scheduled to become effective on 31 Jan 2022. This workshop will discuss the timing of implementation to comply with the regulation and the challenges and opportunities to the clinical supply chain so as to avoid delays and decrease waste. |
| L3 | **The COVID-19 Pandemic & the Innovation it Has Driven** | The Covid pandemic created hurdles and challenges that were difficult to overcome. Thanks to a highly innovative clinical supply chain, we were able to quickly pivot and support clinical studies. This workshop will explain best practices for innovation and creativity and describe some of the solutions that worked well. |
| L4 | **The Covid-19 Pandemic and How Our Industry Has Evolved** | The Covid pandemic created hurdles and challenges that were difficult to overcome. This workshop will provide an overview as to where our industry was pre-pandemic and the systems and practices we have implemented to overcome the pandemic. The discussion will include insights into how much we have evolved, adapted and flexed to be successful. |