GLOBAL CLINICAL SUPPLIES GROUP™

Virtually, Anything is Possible

 # GCSGinittogether

Boot Camp Schedule

Understanding the Essentials of the Clinical Supply Chain

	UK	US East Coast	US West Coast	Title	Description	Communique Room	Instructors
Tuesday, Oct 20	15:00 - 17:30 BST	10:00AM - 12:30 PM ET	7:00AM - 9:30AM PT	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.	Brizzey Meeting Room	Steven Jacobs Rob Pizzie
Wednesday, Oct 21	15:00 - 17:30 BST	10:00AM - 12:30 PM ET	7:00AM - 9:30AM PT				
Thursday, Oct 22	15:00 - 17:30 BST	10:00AM - 12:30 PM ET	7:00AM - 9:30AM PT				

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Essentials of Cell & Gene Therapy Supply Chains

	UK	US East Coast	US West Coast	Title	Description	Communique Room	Instructors
Tuesday, Oct 13	17:00 - 19:10 BST	12:00 PM - 2:10 PM ET	9:00 AM - 11:10 AM PT	Introduction Science & Manufacturing Labeling & Regulatory	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. Supply Chain consideration such as temperature, scalability and regulations for transport will be discussed.	Suvoda Meeting Room	Scott Ohanesian & Lindsay Belcher Paul Ingram Beth Gardner & Lindsey Goller
Wednesday, Oct 14	17:00 - 19:10 BST	12:00 PM - 2:10 PM ET	9:00 AM - 11:10 AM PT	Sites & Systems Clinical to Commercial			Matt Pecora & Akshay Peer Matt Yedwabnick & Matt Pecora
Tuesday, Oct 20	17:00 - 19:10 BST	12:00 PM - 2:10 PM ET	9:00 AM - 11:10 AM PT	Supply Chain Considerations Bio Storage Review			Scott Ohanesian & Sue Lee Rob Jones Scott Ohanesian

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Expanded Access Platforms

	UK	US East Coast	US West Coast	Title	Description	Communique Room	Instructors
Thursday, Oct 15	19:00 - 21:00 BST	2-4PM ET	11AM-1PM PT	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.	Bionical Meeting Room	Gretchen Randlett Terry Iacobucci
Monday, Oct 19	19:00 - 21:00 BST	2-4PM ET	11AM-1PM PT				
Thursday, Oct 22	19:00 - 21:00 BST	2-4PM ET	11AM-1PM PT				
Monday, Oct 26	19:00 - 21:00 GMT	2-4PM ET	11AM-1PM PT				

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Exploring Direct to Patient Clinical Trial Models

	UK	US East Coast	US West Coast	Title	Description	Communique Room	Instructors
Monday, Oct 26	15:30 - 16:40 GMT	10:30 - 11:40 AM ET	7:30 - 8:40 AM PT	Introduction: The Many Faces of Direct-to-Patient	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.	ISS Meeting Room	Mike Sweeney Nicole Gray
Tuesday, Oct 27	15:30 - 16:40 GMT	10:30 - 11:40 AM ET	7:30 - 8:40 AM PT	Direct-to-Patient: Pharmacy Dispense Models			
Thursday, Oct 29	15:30 - 16:40 GMT	10:30 - 11:40 AM ET	7:30 - 8:40 AM PT	Setting up Direct-to-Patient: Working with stakeholders to ensure success			
Monday, Nov 2	15:30 - 16:40 GMT	10:30 - 11:40 AM ET	7:30 - 8:40 AM PT	Direct-to-Patient Data Privacy			
Tuesday, Nov 3	15:30 - 16:40 GMT	10:30 - 11:40 AM ET	7:30 - 8:40 AM PT	The Future of Direct-to-Patient			
Thursday, Nov 5	15:30 - 16:40 GMT	10:30 - 11:40 AM ET	7:30 - 8:40 AM PT	Case Study & Review			

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Import Export for Global Clinical Trials

	UK	US East Coast	US West Coast	Title	Description	Communique Room	Instructors
Monday, Oct 26	16:30 -18:30 GMT	11:30AM - 1:30PM ET	8:30-10:30AM PT	Fundamentals of Import Export	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. The content is broken into 6 distinct sessions to be offered in 2 hour blocks over the course of 4 weeks.	PCI Meeting Room	Ted Bradley Billie Key
Monday, Nov 2	16:30 -18:30 GMT	11:30AM - 1:30PM ET	8:30-10:30AM PT	Importing to & Exporting From the US			Ted Bradley Toni Smith
Monday, Nov 9	16:30-17:30 GMT	11:30 AM - 12:30 PM ET	8:30-9:30AM PT	Importing to & Exporting From Latin American Region			Camila Drigo Paula Pulsoni
Monday, Nov 9	17:30-18:30 GMT	12:30-1:30 PM ET	9:30-10:30AM PT	Importing to & Exporting From Europe & the United Kingdom			Gavin Morgan
Monday, Nov 16	16:30-17:30 GMT	11:30 AM - 12:30 PM ET	8:30-9:30AM PT	Importing to & Exporting From Asia & Pacific Region			Erin Vlack Paul Byrne
Monday, Nov 16	17:30-18:30 GMT	12:30-1:30 PM ET	9:30-10:30AM PT	Importing to & Exporting From Africa & Middle East Region			Rich Nelson

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Boot Camp Schedule

Interactive Response Technology (IRT) in Clinical Supply Chain

	UK	US East Coast	US West Coast	Title	Description	Communique Room	Instructors
Tuesday, Oct 27	16:30 - 18:30 GMT	11:30AM - 1:30PM ET	8:30-10:30AM PT	- History - Workflow Timing - Understanding Critical Study Parameters - Blinding and Unblinding Controls	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.	Brizzey Meeting Room	Jan Pieter Kapelle
Thursday, Oct 29	16:30 - 18:30 GMT	11:30AM - 1:30PM ET	8:30-10:30AM PT	- Randomization Techniques & Trial Designs - Supply Management Models - IMP Status Management - Managing Site & Depot Supply			
Monday, Nov 9	16:30 - 18:30 GMT	11:30AM - 1:30PM ET	8:30-10:30AM PT	- How to calculate your Drug Management Parameters? - End-of-Study, What should you do? - Benefits of using standards			
Wednesday, Nov 11	16:30 - 18:30 GMT	11:30AM - 1:30PM ET	8:30-10:30AM PT	- Key users, Roles, Responsibilities and Needs - Importance of cross-functional collaboration - When (not) to use RTSM? - IMP management without RTSM - Best practices in Sponsor Service Provider Partnership - Technology platform and IRT Integrations - RTSM usage for New Trends and Products - Summary & Review			

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