GCSG 2025
EUROPEAN KNOWLEDGE FORUM
BUDAPEST | OCTOBER 14-16

Begins	Ends	Day 2 - Wednesday 15 October 2025		Location	Learning Objectives	Speaker
07:30	08:30	Registration Open Exhibitor Displays Open				
08:00	08:30	Welcome & Opening Remarks - European GCSG Scholarship Announcement				
08:30	09:30	Keynote Speaker Presentation				
09:30	09:45	Room transfer				
09:45	10:45	Breakout Session 1	WS1 - CGT Supply Chains: Challenges and Best Practices		1. Understanding of both cell and gene therapy supply chains 2. Key stakeholders, considerations, and complexities that encompass CGT supply chains 3. Best practices to manage CGT supply chains effectively and efficiently	
			WS4 - Import\Export and VAT		1. Understand VAT obligations and compliance requirements in international trade. 2. Identify correct documentation and procedures for import and export activities. 3. Implement best practices to minimize VAT-related risks and optimize business efficiency.	
			WS7 - Material Pooling, JIT Labelling and On demand manufacturing (master protocols and adpative designs)		1. Understand the principles and advantages of material pooling and JIT labeling in clinical trials. 2. Explore the role of on-demand manufacturing in supporting adaptive clinical trial designs. 3. Implement best practices to increase supply chain flexibility, reduce waste, and improve overall efficiency in clinical studies.	
			WS10 - Cost of Poor Quality and Lack of Regulatory Focus (Impact on the Clinical Trial Supply Chain)		1. Understand the financial and operational impacts of poor quality management and insufficient regulatory compliance. 2. Identify key risk factors leading to quality issues within the clinical trial supply chain. 3. Develop proactive strategies and best practices to enhance quality, compliance, and overall operational efficiency.	
			WS13 - Essential Project Management skills to influence stakeholders and achieve success		1. Develop advanced communication skills to effectively engage and influence diverse stakeholders. 2. Understand methods for successful negotiation and conflict resolution within project teams. 3. Implement practical project management techniques to enhance stakeholder collaboration and achieve project goals.	
			WS16 - Wastage and safety stocks - measuring, managing and improving		1.Learn accurate techniques for measuring and analyzing wastage within clinical supply chains. 2. Identify root causes of inventory waste and develop strategies to manage and minimize unnecessary safety stock. 3. Implement best practices to balance inventory levels effectively, ensuring patient safety while reducing costs and improving sustainability.	
			WS19 - AI Clinical Trial Discussion		1. AI Integration: Learn about the latest AI technologies and how they can be integrated into clinical trial processes to enhance efficiency and accuracy. 2. Data Analytics: Understand the role of AI in analyzing complex clinical data, identifying patterns, and generating actionable insights. 3. Predictive Modelling: Explore how AI-driven predictive modelling can improve trial design, patient recruitment, and outcome prediction. 4. Operational Efficiency: Discover AI tools that streamline clinical trial operations, reduce costs, and shorten timelines.	
10:45	11:00	Room transfer				
			WS2 - Comparator sourcing strategies - when to use local sourcing, site sourcing or central sourcing		1. Understand key differences and decision criteria for local, site, and central comparator sourcing strategies. 2. Identify best practices to optimize comparator sourcing in clinical trial planning and execution. 3. Learn effective risk management approaches to address regulatory, logistical, and cost-related challenges.	
			WS5 - Ask the Experts: A Candid Discussion on the Challenges of Implementing an Expanded Access Program		This session will take the form of a panel-like discussion, featuring experts from across the industry. Participants will engage in candid conversation about the primary challenges in expanded access (EA): ethics, supply planning and regulatory. Real-life scenarios (failures and successes) will be shared, highlighting how these experts navigated the obstacles.	
			WS8 - Electronic Batch Records		1. Understand regulatory requirements and data integrity considerations for implementing Electronic Batch Records. 2. Identify benefits and challenges associated with transitioning from paper to electronic batch documentation. 3. Develop effective strategies for successful EBR implementation, ensuring compliance, accuracy, and operational efficiency.	

11:00	**12:00**	**Breakout Session 2**	WS11 - Key Factors to Consider When Submitting Your CTA		1. Identify essential regulatory requirements and documentation needed for a successful CTA submission. 2. Recognize common pitfalls and develop strategies to proactively address submission challenges. 3. Apply best practices to streamline the CTA submission process and achieve efficient regulatory approval timelines.	
			WS14 - Supply Chains of Radiopharmaceuticals		1. Understand the specialized logistics, handling, and regulatory requirements unique to radiopharmaceutical supply chains. 2.Identify common challenges and best practices in managing the stability, storage, and timely delivery of radiopharmaceutical products. 3. Develop effective strategies to ensure compliance, product quality, and operational efficiency in radiopharmaceutical distribution.	
			WS20 - Outsourcing and Working with CTS Suppliers: Making a Success of Your Vendor Relationships and Standardisation		1. Effective Outsourcing: Learn the critical factors for successful outsourcing, including selecting the right suppliers and managing contracts effectively. 2. Vendor Relationship Management: Discover methods for fostering strong, collaborative relationships with CTS suppliers to improve communication and coordination. 3.Standardization Practices: Understand the importance of standardization in outsourcing and how to implement best practices to enhance efficiency and consistency. 4.Risk Management: Explore techniques for identifying and mitigating risks associated with outsourcing and vendor relationships to ensure reliability and continuity. 5.Performance Evaluation: Gain insights into monitoring and evaluating the performance of CTS suppliers to ensure compliance with agreements and high-quality outcomes. 6.Networking Opportunities: Connect with industry professionals to exchange knowledge, experiences, and best practices for managing outsourcing and vendor relationships in clinical trials.	
			WS22 - An overview of the challenges and opportunities in Middle East & Africa		1.Understanding Regulatory Challenges: Gain insights into the regulatory landscape in the Middle East and Africa, including common hurdles and best practices for compliance. 2.Logistical Complexities: Learn about the logistical challenges specific to these regions and explore innovative solutions to streamline supply chain operations. 3.Market Dynamics: Understand the market dynamics and economic factors that impact the clinical supply chain in the Middle East and Africa. 4.Strategic Opportunities: Identify strategic opportunities for growth and improvement in the clinical supply chain within these regions. 5.Networking and Collaboration: Connect with industry experts and peers to share experiences, insights, and strategies for overcoming challenges and leveraging opportunities.	
12:00	**13:15**	**Lunch** **Exhibitor Displays Open**				
13:15	**14:15**	**Breakout Session 3**	WS3 - Patient Diversity and reach all patients		1. Recognize and address healthcare disparities among diverse patient groups. 2. Develop strategies to improve cultural competency and inclusive patient communication. 3. Implement best practices for equitable and patient-centered healthcare delivery.	
			WS6 - How sponsors can develop a comprehensive organizational approach to IRT		1. Understand key components and benefits of implementing a comprehensive IRT strategy. 2. Develop effective cross-functional processes for successful IRT integration within an organization. 3. Identify best practices to maximize data quality, operational efficiency, and compliance through IRT systems.	
			WS9 - Improving patient compliance and patient centric digital supply chains		1. Understand how digital supply chain innovations enhance patient compliance and engagement. 2. Identify tools and technologies that support personalized patient interactions and adherence monitoring. 3. Develop strategies for integrating patient-centric digital solutions into clinical supply chain management effectively.	
			WS12 - Navigating internal company transition and change while ensuring clinical trial supply operations remain intact		1. Understand key risks and challenges faced by clinical trial supply operations during internal company transitions. 2. Develop effective communication and change management strategies to minimize disruption and maintain operational continuity. 3. Implement robust contingency plans to sustain supply chain integrity and regulatory compliance throughout organizational change.	
			WS15 - Temperature Excursion Management Solutions		1. Understand the impact of temperature excursions on clinical trial products and regulatory compliance 2. Identify effective monitoring solutions and procedures to quickly detect and manage temperature deviations. 3. Implement proactive strategies and best practices for temperature excursion prevention, investigation, and documentation.	
			WS18 - Sustainability in Clinical Trial Supplies		1. Understand the significance and benefits of integrating sustainability into clinical trial supply operations. 2. Identify practical methods to reduce waste, lower environmental impact, and improve resource efficiency. 3.Develop actionable sustainability strategies compliant with regulatory standards and ethical considerations in clinical supply management.	

			WS21 - Supply planning /agreements between clinical supplies, clinical teams/vendors		1. Importance of Collaboration: Understanding the need for strong collaboration between clinical supplies teams, clinical teams, and vendors to ensure timely and efficient supply delivery. 2. Strategic Planning: Learning the best practices in strategic planning to anticipate and mitigate risks associated with clinical supplies. 3. Inventory Management: Exploring methods for effective inventory management to avoid shortages and surpluses. 4. Regulatory Compliance: Gaining insights into the regulatory requirements and ensuring compliance throughout the supply chain. 5. Roles and Responsibilities: Clarifying the roles and responsibilities of each stakeholder to enhance accountability and streamline processes. 6. Communication Strategies: Developing communication strategies to foster transparency and efficiency between all parties involved.	
14:15	**14:30**	**Room transfer**				
14:30	**15:30**	**Panel/Presentation**				
15:30	**15:45**	**Closing Remarks**				
15:45	**17:30**	**Vendor Reception**				
17:30	**18:00**	**Personal Time**				
18:00	**18:00**	**Departure for GCSG Night Out at Hotel Reception**				
18:30	**23:59**	**GCSG Night Out**				
22:30	**23:59**	**Departures to Hotel**				