Clinical Trial Supply Europe 2018

Developing best practices and incorporating novel technologies to meet the demands of more complex, international clinical trial supply

14th – 15th March 2018 Milan, Italy

19th Annual Clinical Trial Supply Europe Conference

March 14th-15th 2018 | Milan, Italy

2018 Speaking Faculty

Henk Dieteren, Associate Director, Clinical Supply Logistics Expert, **Grunenthal**
Tania Snioch, Director Healthcare, **GS1**
Jan-Pieter Kappelle, Senior Director, Clinical Trial Supplies, **UCB**
Henk Mollee, Senior Director, CTM Manufacturing, **Astellas Pharmaceuticals**
Niklas Mattsson, Lead Comparator Sourcing and Planning, **MSD**
Alison Meyers, Director Clinical Liaison Lead, Clinical Interface**, GlaxoSmithKline**
Florian Clémençon, Senior Clinical Coordinator**, Ipsen**
David Childs, CMC Director, **Shield Theraputics**
Dorte Madsen, Primary Clinical Supply Manager, **Lundbeck**
Wil Cools, Lead Clinical Study Supply, **Galapagos**
Romana Wesenauer, Head of Clinical Supply Chain**, Octapharma**
David Dronneau, Process and Excellence Operation Head, **Sanofi**
Lis Hansen, Clinical Trial Supply Coordinator, **Genmab**
Ross MacRae, Senior Director Clinical Manufacturing, **Pfizer**
Kathrin Machens, Senior Manager Clinical Supplies, **Bayer**
Peter Orosz, Head of Clinical Supply Chain Management & Oncology, **Boehringer Ingelheim**
Thomas Thoma, Head Clinical Trial Supply Europe, **Teva**
Schulze Brita, Executive Director CMC and Regulatory Affairs, **4SC AG**
Pierre Debs, PhD, Chief Executive Officer, **Sprektrum Cannabis**
Luca Russo, VP – Head Clinical Trial Supply, **Janssen**
Erik Meyer, Director Clinical Trial Supply, **Merck**
Michael Stephenson, Associate Director, Clinical Supply Chain Technology and Innovation, **Janssen**
Ignacio Gomez-Arroyo Bernabeu, Senior Associate Engineer, Clinical Supply Chain Technology and Innovation, **Janssen**
Nicola Barnes, Senior Director, Clinical Supply Packaging, **Pfizer**
Ricardo Lima, Head of Pharmaceutical Development, **Bial**
Asim Khan, Senior Manager, Clinical Research Pharmacy Services, **Amgen**
Alex Robertson, Senior Director, Supply Chain Management, **AstraZeneca**
Massimo Eli, Clinical Supply Regional Lead, **MSD**

Clinical Trial Supply Europe 2018

Developing best practices and incorporating novel technologies to meet the demands of more complex, international clinical trial supply

14th – 15th March 2018 Milan, Italy

Clinical Trial Supply Europe 2018 | Milan, Italy **Day One | 14th March 2018**	
07:45	Registration Sponsor: CLINIGEN Clinical Trial Services Lanyard Sponsor: GNH INDIA Global Leader, Local Partner
08:10	**Chairman's opening remarks**
08:15	**Investigating how moving from a generic towards a personalised medicine model will affect your supply chain requirements** • Appreciating industries move from a general towards a personal medicine model and how this will alter supply chain logistics • Exploring how a reduced shelf life will require a more local approach to drug distribution to ensure trials are successful • Uncovering manufacturing requirements needed to ensure trial drugs can be personalised and costs associated with this • Review how current processes do not align with a personalised medicine model and suggest what changes need to be carried out to ensure you can supply sites and patients without delay • Design labels which can be easily interpreted by patients to ensure adherence and guarantee trial success **Luca Russo**, VP – Head Clinical Trial Supply, **Janssen**
08:45	**Transportation Challenges in Cell & Gene Therapy and Risk Mitigation methods** • Considering differences between Cell and Gene Therapy clinical trials and how these differ • Learnings from 10 years of experience in CGT clinical trials; risk mitigation methods • Assessing best practices in CGT trials • Exploring emerging technologies that will improve CGT trials, and risk mitigation tools **Korhan Imer**, WEMEA Lead for Cell and Gene Therapy, **World Courier**
09:15	**Maximising forecasting tools available to sponsors to ensure your trials are accurately planned and disruptions can be handled with minimal impact** • Promoting historic data as a tool which can enable higher trial accuracy by applying past lessons to future trials • Outlining which responsive forecasting systems are available which can best react to fluctuations in the supply chain and enable you to act in real time • Exploring how patient enrolment data can enable you to improve your forecasting and ensure resources are distributed when and where needed • Considering whether building an internal forecasting tool is more suitable for your company than relying on a software made by a third party • Investigating how Enterprise Resource Planning tools can improve your forecasting as an alternative to current software systems

	Thomas Thoma, Head Clinical Trial Supply Europe, **Teva**	
09:45	**Improving Processes for Temperature Traceability from Packaging to Patient** • Understanding challenges and the increasing need for innovative solutions • Outlining innovative and user friendly technologies that can be applied today • Exploring example case studies and benefits of optimal solutions **Tim Gilbert,** Senior Director, Product Management, Randomization and Trial Supply Management, **PAREXEL**	
10:15	**Morning refreshments and networking**	
	Clinical Supply Operations	**Clinical Supply Technology**
10:45	**Exploring various comparator sourcing models to determine which is most cost effective and causes least disruption to your supply** • Charting drive towards comparator country source decision • Evaluating comparator sourcing model that is most efficient to guarantee your supply chain demand • Unpacking whether local or central comparator sourcing is the right model for your study to stay within budget • Examining costs-reduction methods by aggregating orders for the whole program instead of doing these by individual protocols to ensure you have enough supply • Outlining long-term forecasting tools as a tool to reduce timelines disruptions, stabilize comparator prices and ensure you are adequately stocked **Niklas Mattsson**, Lead Comparator Sourcing and Planning, **MSD**	**Developing a Just-in-Time labelling strategy for your global clinical trials to minimize costs and prevent trial delays** • Assessing effectiveness of Just-in-Time labelling in improving flexibility to maximise accuracy of your clinical trials • Establishing cost-effectiveness of regional versus local labelling when trials are taking place in different regions to maximise efficiency • Outlining technology systems available to aggregate data label information and expedite translation to streamline trial times • Evaluating ways through which expiry dates can be managed without the need for booklet labels • Emphasizing the need to improve communications between operations and supply teams to ensure labels are correctly designed for designated trial countries **Michael Stephenson**, Associate Director, Clinical Supply Chain Technology and Innovation, **Janssen** **Ignacio Gomez-Arroyo Bernabeu**, Senior Associate Engineer, Clinical Supply Chain Technology and Innovation, **Janssen**

Clinical Trial Supply Europe 2018

Developing best practices and incorporating novel technologies to meet the demands of more complex, international clinical trial supply

14th – 15th March 2018 Milan, Italy

11:15	**Session Reserved for PCI**	**Session Reserved for Oracle**
11:45	**The role of global standards to help enable clinical supply chain efficiency and accuracy** • The benefits from application of globally standardised identifiers and barcodes for clinical trial products • What can be done to leverage commercial supply chain learnings • Perspectives from industry stakeholders and next steps **Tania Snioch**, Director Healthcare, **GS1**	**Determining the value of building internal IRT systems vs purchasing 'off-the-shelf'** • Appreciating the investment of time needed by both sponsors and vendors when partnering to design a custom-made IRT system and determining its benefits and drawbacks • Outlining how specialised IRT vendors offer technical expertise which can save time and money • Highlighting ways through which custom made systems can ensure regulatory compliance and prevent problems throughout the studies development • Considering whether a 'one-size-fits-all' IRT system is suitable for your studies given study complexity and patient enrolment fluctuations • Presenting IRT systems as a viable investment for a small biotech to improve your clinical trial **Florian Clémençon**, Senior Clinical Coordinator**, Ipsen**
12:15	**Workshop: Busting Myths - Comparator sourcing from ROW markets** • Increasing demand for comparators / RLDs in traditional markets - US and EU requires companies to develop GxP compliant strategies for dealing with shortages when sourcing comparators from RoW markets. • Considering RoW markets such as India for Comparator Sourcing requirements allows large quantities for any given Comparator / Innovator • Large quantities of Comparators are no longer available easily from traditional markets, it has become important to understand regulatory frame work behind the licensing of innovators in ROW markets means that single batch / multiple batch requirements easier to handle.	**RTSM + CSM = RCSM: the best of both worlds to streamline your clinical trials** • Combining the power of IRT (RTSM) and supply chain management solution (CSM) enables Biopharmaceutical companies to shave time and cost off clinical trials implementation • Forecasting within IRT; how this technology is a solution which fits all sizes, biotech and large pharma alike, to minimize drug wastage • Streamlining IRT supply management to avoid data and system functionalities duplication • Advancing Cold chain management: Aggregate Longitudinal Dataset allows for true temperature monitoring and greater trial safety

	• Innovators ask too many questions and put too many restrictions when sourcing from US / EU markets which shortens lead times so understanding best practises in Anti-Counterfeiting for RoW markets can enable cost advantages of approximately 40% as compared to US / EU markets **Dr. Piyush Gupta**, Director - Business Development, **GNH India**	**Representative from Bracket**
12:45	**Lunch and Networking**	
14:00	**Exploring European Union Annex 13 and its effect on the industry's operating model** • Unpacking what annex 13 means for industry to be able to determine compliance with regulatory expectations • Showcasing complications of labelling primary and secondary and how this can compromise trial integrity and risk trail data • Examining costs associated with labelling both primary and secondary drug supplies and its effect on trial budgets • Exploring e-labels as a solution to this regulatory requirement while also improving trial safety • Sharing best practice in placebo design to lower overall trial costs and improve your trial data **David Dronneau**, Process and Excellence Operation Head, **Sanofi**	**Case Study: Determining which IRT vendor is the right one for your company to ensure your supply chain is adequately monitored** • Assessing key differences between IRT vendors to ensure you partner with the one which is most suited to the trials you are running • Determining what limitations vendors have with regards to what their technology can deliver to prevent unforeseen roadblocks in your study requirements • Designing proactive strategies which can be put in place to counteract limits to current IRT capabilities • Considering whether a specialized IRT vendor of a full services provider is best for your trial design • Exploring key aspects to consider when selecting an IRT system to guarantee your partners system is compatible with your study **Brita Schulze**, Executive Director CMC and Regulatory Affairs, **4SC AG**
14:30	**Session Reserved for PRA**	**Session Reserved for Cenduit**
15:00	**Establishing communication strategies across in-house clinical teams to maximise efficiency, reduce resource wastage and expedite trial times** • Appreciating how each departments actions have a knock on effect on the	**Investigator Initiated Studies – a challenge for supply with IMPs?** • Understanding of regulatory background • What has to be considered to avoid hurdles? • Supply chain options to ensure smooth

	whole supply chain and suggest approaches which can anticipate problems before these arise • Sharing up-to date information between in-house supply and operations teams so timelines are adhered to effectively • Ensuring departmental priorities are effectively outlines to guarantee internal awareness and prevent silos • Harnessing technology's power to create communication strategies which can inform about changes to trial supply in real time and avoid inaccurate resource allocation • Evaluating whether horizontal reporting structures can improve departmental relationships by establishing a clear responsibility frameworks **David Childs**, Director CMC, **Shield Pharma**	provision of IMPs **Peter Orosz**, Head of Clinical Supply Chain Management & Oncology, **Boehringer Ingelheim**
15:30	**Session Reserved for Durbin**	**Exploring the latest development in Smart Labels to establish IOT (internet-of-things) and Industry 4.0 in Clinical Trials** • Using developments in Smart Labels to implement remote expiry updates to create greater efficiency in your trial • Solving Annex VI requirements concerning expiry updates with the Faubel-Med® Label • Support Time-Temperature-Monitoring as well as Patient-Compliance with IOT • Optimizing the logistic of the clinical trial supply chain by using Industry 4.0 Applications **Frank Jaeger**, Managing Director, **Faubel**
16:00	**Afternoon refreshments and networking**	
16:30	**Case Study: Highlighting results of automated receipt process of temperature monitored shipments in a pilot clinical trial** • Exploring systems integration approach has been achieved • Unpacking challenges during set up of the automated process	**Exploring transportation complexities when shipping oncology material at 80°C and 2-8°C** • Exploring ways to centralize data monitoring of temperature excursions between shipping companies and clinical supply teams • Designing systems which ensure all excur-

	• Comparing results from pilot clinical trial with trials not using this process • Considering highlights on future actions **Henk Dieteren**, Associate Director, Clinical Supply Logistics Expert, **Grunenthal**	sions can be identified by lot so to comply with Quality Assurance expectations • Addressing the need to improve controlled room temperature technologies given increasing regulatory demands in this area • Emphasizing need for accurate monitoring of clinical supplies to ensure integrity of trial data **Lis Hansen**, Clinical Trial Supply Coordinator, **Genmab**
17:15	**Session Reserved for Marken**	**Session Reserved for End Point**
17:45	**Outlining ways to prepare your current depot strategy and comply with upcoming regulatory challenges** • Enhancing knowledge on depot management and logistics to improve your current mapping strategy • Presenting methods to ensure all your depots are adequately equipped to comply with upcoming regulatory changes to Annex 13 and GMD revisions • Assessing the impact of Brexit on UK and European trials to prepare for changes in the region affecting your clinical trial • Investigating variations in regional differences on your depot strategy and designing comprehensive mapping mechanisms to overcome these when conducting global clinical trials • Examining ways by which IVRS can be integrated between depots and sponsors to improve drug accountability and minimize administrative burdens **Alex Robertson**, Senior Director, Supply Chain Management, **AstraZeneca**	**Reviewing Clinical Trial Regulation EU 536/2014 and its effect on how clinical trials are conducted** • Unpacking differences from the current 2001 EU directive • Discovering what different demands are placed on sponsors & manufacturers of Clinical supplies • Reviewing regulatory impact from a Submission standpoint? (Re. Chapter IX and X) • Exploring new labeling requirements for IMPs and AxMPs (Chapter X and Annex VI) **Massimo Eli**, Clinical Supply Regional Lead, **MSD**
18:15	**Chairman's summation and close of day one**	

Clinical Trial Supply Europe 2018

Developing best practices and incorporating novel technologies to meet the demands of more complex, international clinical trial supply

14th – 15th March 2018 Milan, Italy

Clinical Trial Supply Europe 2018 Day Two –15th March 2018		
08:30	Registration Sponsor: CLINIGEN Clinical Trial Services	Lanyard Sponsor: GNH INDIA Global Leader. Local Partner.
08:50	**Chair's opening remarks**	
	Clinical Supply Operations	**Clinical Supply Technology**
09:00	**Reviewing how to effectively carry out blinded clinical trials in the 21st Century and whether these are still possible** • Appreciating complexities of carrying out blinded trials due to greater patient connectivity and how this can affect trial results • Determining ways sponsors can work around greater patient interaction to prevent negative impacts on trial results • Consider whether blinding clinical trials is needed when comparing commercialised versus trial drugs • Exploring currently available blinding strategies to prevent patient groups from compromising results • Sharing best practice blinding success stories to lower your supply chain costs	**Patient Centric Strategies for Supply Chain** • Exploring current patient centric strategies available for IP supply • Evaluating which patient centric initiatives are right for your study and company • Working collaboratively with drug development colleagues to achieve patient centric Supply Chain **Alison Meyers,** Clinical Liaison, Clinical Interface, **GlaxoSmithKline**
09:30	**Session Reserved for Catalent**	**Session Reserved for BioClinica**

10:00	**Key CMC Success Strategies when executing in-house Biopharma manufacturing vs. outsourcing to CMO's** • Reviewing different strategies used when leveraging in-house Biopharma manufacturing vs. outsourcing to CMO's • Assessing how a cross functional CMC Subject Matter Experts in establishing of a high performance team is a critical strategy for success with in-house or CMO Biopharma manufacturing. • Establishing how correct levels of experience, FTE, and consultant's strategy will reduce the overall cost of CMC while maintaining the dynamic clinical launch strategy • Exploring High Performance Work Team leverages an Integrated product launch schedule (defined CMC, resources, CMO's/ Internal MFG, supply chain, costs, NDA, and PAI activities). • Aligning with Regulatory/ Quality in establishing the CMC strategy (internal or external CMC) that supports your NDA launch strategy **Ross MacRae**, Senior Director Clinical Manufacturing, **Pfizer**	**Digitizing clinical manufacturing; reducing waste, minimize human error and improving efficiency** • Promoting digital systems when carrying out clinical manufacturing as a mechanism to prevent human error and reduce resource wastage • Harnessing the power of digitisation to enable data aggregation which can be used to retroactively improve your manufacturing strategy • Aligning manufacturing systems to ensure harmonisation and improve working flow capabilities so to maximise efficiency • Adopting a continuous manufacturing approach to your clinical supply chain to improve drug availability and on-time delivery • Appreciating how a digital manufacturing can streamline your data integrity by coalescing data into a simple system **Henk Mollee**, Senior Director, CTM Manufacturing, **Astellas Pharmaceuticals**
10:30	**Session Reserved for Almac**	**Session reserved for sponsor**
11:00	**Morning refreshment**	

Clinical Trial Supply Europe 2018

Developing best practices and incorporating novel technologies to meet the demands of more complex, international clinical trial supply

14th – 15th March 2018 Milan, Italy

11:30	**Ensuring your packaging is compliant with current regulations to minimize delays and achieve a swift delivery** • Examining what different packaging needs are required for various types of clinical trial materials to ensure you are packaging correctly • Acknowledging impacts of Annex 13 on packaging costs and what timeframe you'll require to prepare • Assessing methods to prepare packaging materials before all countries have been selected for your trials • Determining benefits of manual vs. automated packaging processes as a cost saving measure when engaging in multi-country trials • Considering the possibility of amalgamating packaging and inventory systems management into one department to avoid duplicity of task **Nicola Barnes**, Senior Director, Clinical Supply Packaging, **Pfizer**	**Innovations in Clinical Supply Management – what's new for 2018** • Outlining key drivers for improvement and innovation in the clinical supply chain • Exploring opportunities for the evaluation of trends and technologies in the clinical supply business • Designing a system for balancing effort/investment versus value of an innovative idea • Introduction of a QR code used for additional information for site and patient education **Kathrin Machens**, Senior Manager Clinical Supplies, **Bayer**
12:00	**Session Reserved for Sponsor**	**Visualizing your clinical supply data at the portfolio level to guide strategic & operational decision making** • Exploring the advantages of having a portfolio level view on clinical supplies data • Discovering how business intelligence dashboards can help identify areas in the trial portfolio needing attention • Investigating the benefit of different metrics for clinical supplies management through case studies **Sylvia Haller,** Life Sciences Engagement Manager, **N-SIDE**
12:30	**Panel: Exploring regulatory implication of Brexit when carrying out clinical trials in the United Kingdom** • Anticipating timeframes for regulatory	**Panel: Aligning systems to better manage drug returns and ensure the whole of your supply chain is adhering to regulatory requirements** • Promoting integration of track and trace

	change arising from negotiations to ensure industry preparedness • Recognizing potential requirement for two trial applications in Europe and UK and how this could impact study start-up times • Exploring current European Union regulations and which aspects will be absorbed by UK to enable future planning • Assessing possible depot moves to mainland Europe and the impact for sponsors and vendors ability to carry out European clinical trials • Exploring EMA's relocation and its potential effect on future trial approvals to adequately plan for trial timeline disruptions	into IRT systems to improve drug accountability accuracy and enable sponsors to manage returns effectively • Encourage sponsors and sites to integrate systems to avoid task duplicity and reduce human errors • Comparing centralized and trial-site specific ways to carry out drug destruction and assess their cost-effectiveness • Examining regulatory differences between EU and USA with regards to IMP destruction to ensure sponsors are compliant with local variations • Investigating how increased pressure on industry to ensure reverse supply chain protocols will affect your clinical trials **Ricardo Lima**, Head of Pharmaceutical Development, **Bial**
13:00	**Lunch and networking**	
14:00	**Considering methods to achieve last mile delivery; enhancing courier and import/export knowledge to minimise holdups and delays** • Unpacking which speciality couriers and shippers are best suited for your products needs to improve your supply chain delivery • Ensuring import considerations are incorporating in to your planning stage to maximise timely delivery • Comparing value of using air, sea and land when shipping your drugs in different regions to ensure best value for money • Designing strategies to minimize holdups that arise from regulatory inspections when import-ing/exporting your trial supplies and avoid delays • Evaluating advantages and disadvantages of manufacturing in one or multiple countries from an import/export perspective to ascertain the best strategy **Pierre Debs, PhD**, Chief Executive Officer, **Sprektrum Cannabis**	
14:30	**Panel: Improving temperature monitoring with IRT; ensuring your supplies are adequately stored while in transit and on site** • Acknowledge the importance of temperature monitoring for your clinical trials and the implications inadequate supervision can have on patient safety • Harnessing IRT technology to monitor temperature fluctuations throughout the shipping process and account for any damages • Designing technologies which can adequately track temperature monitors at site by sponsors to ensure trial drug properties are not compromised • Integrate temperature monitoring within IRT systems to guarantee that supply managers can	

	be alerted when supplies are incorrectly stored • Harmonizing technology systems between shipping companies, sites and sponsors so that reporting can be carried out seamlessly and reduce drug wastages **Jasmin Hellwig**, Associate Director Comparator Sourcing, **MSD** **Asim Khan**, Senior Manager, Clinical Research Pharmacy Services, **Amgen**
15:00	**Afternoon refreshments**
15:30	**Speaker Hosted Roundtables** Interactive roundtable sessions offer a unique opportunity to come together with your peers to share best practice and develop solutions to critical challenges facing the industry as a whole. Hosted by industry experts and each focused on a single issue, roundtables are an exciting, interactive way to build your personal network and learn from the experience and expertise of others. Each roundtable session lasts for 45 minutes, and delegates may attend up to 2 roundtables
Roundtable 1	**Continuing the discussion on GDP regulation** **Maurizio Caschera,** Quality Responsible Person (Vaccines)**, MSD**
Roundtable 2	**Session Reserved for Peli Biothermal**
Roundtable 3	**Discussing the complexities of blinding in the digital age and its implication for sponsor led studies** **Dorte Madsen,** Primary Clinical Supply Manager, **Lundbeck**
Roundtable 4	**Unpacking how patient centricity will change the clinical supply chain and how to prepare for this** **Wil Cools,** Lead Clinical Study Supply, **Galapagos**
Roundtable 5	**Aligning supply and IT departments to ensure internal IRT systems are designed to meet protocol requirements and prevent delays** **Erik Meyer**, Director Clinical Trial Supply, **Merck**
Roundtable 6	**Exploring ways to digitize your supply chain and expedite the R&D process to improve your competitiveness** **Romana Wesenauer,** Head of Clinical Supply Chain**, Octapharma**
17:00	**Chair's summation and close of conference**