

Clinical Trial Supply Europe

21st – 23rd January 2015

Frankfurt, Germany

**PHARMA IQ
DIVISION OF
IQPC LTD.**

This summit is produced and organised by the international company IQPC Ltd.

Draft Agenda | Topics and speakers may change in the course of
programme development

Summit programme

Dear colleagues,

Join us in celebrating the **5th Anniversary** of this unconventional **CTS Europe Summit** in **Frankfurt, Germany 21-23 January 2015** to help you set your New Year goals and implement clear strategies for achieving these.

Being the first **European Clinical Trial Supply** event in the year **Pharma IQ** together with executive panel of speakers evaluates the achievements of 2014 and sets a direction for 2015 allowing you to think about the year ahead. This annual gathering sets the bar for enabling you to stay ahead of the game.

Over the past 5 years of us analysing this market, we can honestly say that huge progress has been made! However, what does the future hold and **why should we continue talking about GDP standards, labelling practice, forecasting and comparator sourcing?**

By bringing together regulatory experts, industry leaders and innovative services Pharma IQ CTS Summit faces the challenges of clinical supply head on and provides you with essential knowledge that can bring you quicker results and make critical decisions easier to solve.

Key highlights of CTS Europe Summit 2015:

In January 2015, join Pharma IQ and 120+ clinical trial supply experts to learn about...

- Effectively sourcing comparators and shipping for clinical trials
- Reducing costs and improving cost efficiency in clinical trial supply
- Forecasting and simulating clinical trial supply
- Regulatory updates on labelling and repackaging for clinical trial supply
- Reviewing the procedure for recalling the product back from the clinical trial
- Educating your site staff about the storage and preparing for audit

Interactive formats to get you thinking:

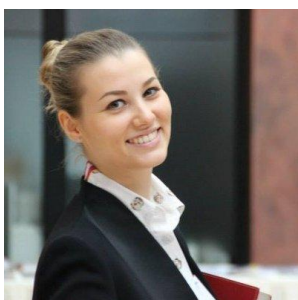
Head-to-head session: CRO vs. pharma – What are the differences in their CTS approach and what can we learn from one another?

Consultancy roundtable game: work in small groups to identify 5 challenges that you face on a day to day basis and then pass them on to the next team to become a consultant and help another team to solve their challenges

Cost saving panel: How to reduce costs by looking at refining 4 key areas of your supply chain?

On-stage interview with a regulator: it's your chance to find out about the future of CTS

I look forward to meeting you in Frankfurt soon!



Anastasia Reshetnikova

Summit Director - Clinical Trial Supply Europe

P.S.: Check out our free online resources including interviews, interactive info graphic, e-book and much more that we have specially collected and prepared for you to enjoy

www.clinicalsupplyeurope.com

Expert speaker panel 2015 includes:

- Svetlana Zavidova, Executive Director, **Association of Clinical Trials Organizations (ACTO)**
- Steve Jacobs, Chair, **Global Clinical Supplies Group**
- Angelique Van Den Berg, Senior Manager Clinical Supply Chain, **Amgen Europe**
- Eric Leire, CEO, **DanDrit Biotec**
- Gianpiero Lorusso, Supply Chain Director, Global Manufacturing & Supply, **Merck Serono**
- Eef Verhaegen, Associate Director Global Clinical Supplies, **PPD International**
- Helle Aagaard-Kirkeby, Primary Clinical Supply Manager, Clinical Supply Development, **Lundbeck**
- Dr. Peter Orosz, Head of Clinical Supply Chain Management Oncology, **Boehringer Ingelheim**
- Jens Mattuschka, Vice President, CLS Worldwide Operations, **PAREXEL International**
- Sascha Sonnenberg, Vice President, Commercial Operations, **Marken**
- Robert Donnell, Head of Business Development, **Durbin**
- Sue Lee, Technical Portfolio Manager, **World Courier**

Day One: Workshops

Wednesday, 21st January 2015

09:00

Registration and morning welcome refreshments

09:30 Workshop A: Clinical trial supply distribution strategies

- How to connect return and destruction strategies to your supply strategy
- Innovations and regulations that will impact the clinical trial supply chain

The workshop is aimed at assessing the current challenges in transporting clinical trial products to remote and less developed clinical sites. Sharing with the industry how these are addressed by the 3rd parties together with the supply chain managers in a collaborative approach to ensure the communication, processes and standards are in place to maintain the integrity and quality of the time and temperature sensitive products along the supply chain. Learn how to effectively plan and manage your supply chain with the leading professionals by thinking about many other risks that may occur along the way.



Sascha Sonnenberg, Vice President, Commercial Operations, Marken

12:00

Sandwich lunch break

12:40 Workshop B: Examining strategies for effective labelling of different clinical trial products

- Understanding the effect of changing regulations on the labelling practice
- Analysing the distribution and storage requirements to select the right label that won't be affected by the temperature requirements
- Investing in advanced labelling to ensure the protection of the product and its traceability
- Comparing labels against one another to ensure no variations between the new batches of labels when printing in different languages and for different clinical sites
- Thinking of individual label designs for different patients and how these can be produced effectively

This workshop is dedicated to real life case studies involving practical examples and strategies for effectively organising labelling process. This interactive format, open discussion session will enable its attendees to understand how to control and improve their current labelling practice and which partners to work with.

14:10

End of workshop day

Summit programme

Day Two: Main Summit Thursday, 22nd January 2015

08:00 Registration and morning welcome refreshments

08:30 Chairman opening remarks and direction setting for the summit
Steve Jacobs, Chair, Global Clinical Supplies Group

Update on the current regulatory standards and working within them

08:40 On-stage interview with a regulatory authority body on the future of temperature controlled clinical products and how they will be affected by the GDP updates and changes in standards

This is your chance to find out about the future of GDP and GMP standards that will be affecting your supply chain. Hear from the regulatory authorities and their work towards the CTS industry. Gather their uptake on the emerging markets and what they believe is the best route of operating within the less developed areas.

Steve Jacobs, Chair, Global Clinical Supplies Group

09:20 Panel Discussion: Right Drug. Right Patient. Right Time. Right Temperature.

Clinical research is an increasingly global endeavour and clinical trials logistics have evolved to supply the global market bringing a host of interesting problems. Our everyday challenge is how to get things right and this panel discussion will bring together industry professionals to discuss their trials, tribulations and some of the solutions that they employ for success.

Panel Moderator:



Sue Lee, Technical Portfolio Manager, World Courier

Jens Mattuschka, Vice President, CLS Worldwide Operations, PAREXEL International

10:00 People Bingo: Interactive Speed Networking – Business Cards at the Ready!

A highlight of IQPC events and now at CTS Europe Summit for you to get involved in! Be ready to meet your peers and share best practice. You will have several 2 minute conversations to enable you to network with multiple new contacts.

Please share:

- 1) Who you are
- 2) Scope of your job role
- 3) What you plan to achieve from attending this conference
- 4) Your #1 Challenge

10:20 Networking Coffee Break

Improving efficiency by managing and reducing costs

10:40 Panel Discussion: Understanding your supply chain and what goes into it to efficiently manage costs

- Mapping out your operational activity and reviewing your forecast data analysis to understand what is essential
- Examining areas that will drive your business forward and capitalising on them
- Working closely with your finance department and consulting with them on the ways of bringing wastage measurements to the minimum

Summit programme

11:20 Planning and forecasting for clinical trials to minimise disruptions in supply chain and to ensure the overall success

- Simulating and piloting clinical trials for new products in emerging markets
- Examining methods for successful data collection and analysis to implement better cost control, reduce wastage and improve supply chain
- Applying smart IT systems that will save you time and money on data analysis and planning

12:00 Improving efficiency of your clinical trial supply chain by outsourcing various functions

- Analysing functions within your supply chain to identify those that are time consuming or costly
- Understanding reasons and benefits for outsourcing various functions that could make your supply chain more effective
- Decentralising your supply chain by passing more responsibility to the local franchisees or 3rd parties

12:40

Networking Lunch Break

14:00

Round Tables Section

Understanding emerging markets by discussing their challenges and learning from each other's best practice of working in areas such as Africa, China, India, Brazil

There will be 4 tables on each region where challenges and opportunities will be addressed head on and examined from a case-study perspective.

Table 1: India



Table 2: China



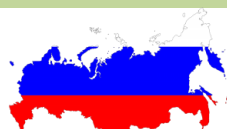
Table 3: Brazil



Table 4: Africa



Table 5: Russia



*Svetlana Zavidova, Executive Director,
Association of Clinical Trials Organizations
(ACTO)*

14:40

Table 1:

Ensuring the security of your clinical trial supply chain

- Which security aspects should you be aware of?
- Creating better contingency plans in case of emergency
- Working closely with your logistics partners to ensure a holistic approach to the security of your distribution
- Discussing how the logistics provider can ensure safety for your supply chain, especially in the less developed areas

Table 3:

Planning for unforeseeable circumstances and managing a crisis before it occurs by implementing contingency planning in the early stages of supply chain planning

- Brainstorming aspects of your supply chain that might need a back up and thinking of a plan B
- Gathering results from the forecast to eliminate the possibility of interrupting your clinical trial for the reason of undersupply
- Taking into the account security aspects and foreseeing ways of managing these
- Preparing for potential distribution and storage challenges that may occur on the way

Table 2:

Distribution strategies



**Sascha Sonnenberg, Vice President,
Commercial, Marken**

Table 4:

Educating site staff about distribution and storage

- Testing the best methods for educating new site staff about GDP standards to ensure quality of the last mile
- Preparing for audits and running them onsite: What should you be looking for?
- Examining deviations and understanding the procedure of replacing the products in the clinical trial

Summit programme

15:20

Networking Coffee Break

15:40

Table 1:

What level of finished drug product waste is acceptable to your organisation?

- What is the definition of product scrap?
- Who is accountable for scrap?
- What is needed to reduce scrap?

Angelique Van Den Berg, Senior Manager Clinical Supply Chain, Amgen Europe

Table 2:

Why comparator sourcing is still a challenge?

- Brainstorming ideas for various routes of sourcing comparator products
- Understand the complete process of the documentation process for comparator sourcing
- Working together with 3rd parties to help you run a full study on the comparator products, modify them and ship them to the needed site



Robert Donnell, Head of Business Development, Durbin

Table3:

Forming long lasting partnerships with your suppliers to ensure efficiency within your supply chain

- Examining categories for selecting suppliers to ensure long lasting relationships
- Designing service level agreements and standard operating procedures together with your service provider
- Reviewing current performance metrics and agreeing on the corrective actions to implement new systems and contract improvements

Gianpiero Lorusso, Supply Chain Director, Global Manufacturing & Supply, Merck Serono

Table 4:

Understanding specific challenges for smaller biotech companies and competing on a global scale

- Examining the pros and cons of performing on a small scale and ways of improving profits
- Shipping and storing bio material and bio products that require extreme temperature control

16:20

IMPs for investigator initiated studies

- What has to be considered?
- Understanding the regulatory background
- Analysing the lean supply chain management

Dr. Peter Orosz, Head of Clinical Supply Chain Management Oncology, Boehringer Ingelheim

Summit programme

17:00 Drinks Reception and Clinical Supply Fairground

–

19:00



The lumps and bumps of the clinical supply chain are somewhat like a fairground. You have your ups and your downs, travel the world and everything is always crazy busy. After a jam-packed full day of case studies and learning, use this informal fun networking platform to unwind and discuss the day's event.

Relax and network your way through our fairground themed exhibition. Each of our exhibitors play host to different games and activities - every game you win, you get a stamp! Complete the fairground themed map and play the games to be entered into the prize draw with your chance to win one of our 3 top prizes!

Catch up with colleagues and connect with new individuals as you discuss the latest challenges and solutions in the clinical supply fairground!

Summit programme

Day Three: Main Summit Friday, 23rd January 2015

08:30 Registration and morning welcome refreshments

09:00 Chairman recap of day two

Steve Jacobs, Chair, Global Clinical Supplies Group

Understanding different approaches to organising CTS and improving internal communication

09:10 Head to head session: pharma vs. CRO

What are the differences in their CTS approach and what can we learn from each other?

There is an on-going debate regarding the organisation and management of CTS within pharmaceutical companies and CRO companies, but how different is it? This session is designed in the way so that you can hear from both sides and gather the best practical examples on building partnerships and improving your clinical trial supply

CRO Panellists:

Eef Verhaegen, Associate Director Global Clinical Supplies, PPD International

Pharma companies:

Helle Aagaard-Kirkeby, Primary Clinical Supply Manager, Clinical Supply Development, Lundbeck

09:50 Improving internal communication between stakeholders to ensure smooth operation of your supply chain

- Understanding how your supply chain is affected by poor communication on day-to-day basis
- Analysing the main processes of CTS that need to be communicated effectively internally
- Examining stakeholders and their input into your clinical supply chain management
- Establishing best routes to communication by setting clear KPI

10:30 Networking Coffee Break

Reviewing labelling standards and exploring new trends

11:00 Looking at the regulatory updates on the Clinical Trial Directives to understand how these will affect the clinical trial supply chain and in particular the labelling and packaging procedures

“On 16th April 2014 the new Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC was adopted, and published in the Official Journal on 27 May 2014. “On 16th April 2014 the new Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC was adopted, and published in the Official Journal on 27 May 2014. It entered into force on 16 June 2014 but will apply no earlier than 28 May 2016”

Summit programme

11:40 Examining the benefits of e-labelling for clinical trial to ensure accurate data collection and secure information distribution

- Using correct barcodes to identify pack numbers and kit types throughout the supply chain
- Automating label checking systems by considering flexibility, traceability and batch turnaround times
- Enabling patient and site staff to access information and instructions more quickly
- Analysing the downturns of e-labelling for clinical trials to understand how these could be managed

12:20

Networking Lunch Break

13:30 Reviewing the reconciliation and destruction process and how it may change according to the location

- Revising internal procedures for recalling the product back from the trial
- Analysing various regulations in relationship to recalling and destruction of clinical trial products and how they are different across different areas
- Understanding the procedure for reconciliation and destruction in different areas where the traditional standards don't apply

14:10 Thinking about compassionate use clinical trial drugs in a broader perspective and effectively planning for it

- Examining clinical trials where the period of testing was prolonged for the reason of compassionate use
- Does this principal apply to the oncology products mostly or can we learn from this experience to make better forecasts for similar drugs and biotech products?
- Understanding the major challenges for supplying compassionate use patients with the products in the longer term

Eric Leire, CEO, DanDrit Biotech

14:50

Networking Coffee Break

15:10 Consultancy roundtable game:

Work in small groups to identify 5 challenges that you face on day to day basis and then pass them onto the next team. In return receive 5 of their challenges that you will need to solve in the next 20-30 minutes as a team and provide an onstage feedback.

In exchange you will get some suggestion for your own 5 challenges that you have brainstormed in the beginning of the session. This way all summit attendees will be able to come out with a list of potential solutions.

16:40

Sponsor Prize Draw for the Funfair Night

Chairman Closing Remarks

17:10

End of Summit

Sponsorship Opportunities:

What Makes the IQPC Sponsorship Package Superior to All Others?

There's really no magic, it is merely patient attention to what our sponsorship customers want, expect, need and value. Every sponsor wants to create customers, develop qualified sales leads, convert leads into sales and retain customers. Our tailored sponsorship packages help you to achieve these objectives.

Engage and influence key decision makers

Work with us before, during, and after the event to engage your audience. Our reach across the Construction industry is unprecedented.

Benefit from:

- Thought leadership
- Brand awareness
- Face to face meetings
- More data
- New prospects



How to get involved

For existing sponsorship opportunities please contact **Gal Cohen** on **+44 (0) 207 368 9300** or email to sponsorship@iqpc.co.uk.

Sponsors and Exhibitors of CTS Europe Summit 2015:



Temperature Sensitive Solutions (TSS)

Website: www.tss.se

Temperature Sensitive Solutions (TSS) offers Temperature Data loggers and a high end Temperature Monitoring System (CCIS) that meets the need for Clinical Trial Entities, CRO's as well as general Pharma logistics. TSS and it's key global customers have together taken the important step to break old patterns and solve tomorrow's challenges. CCIS provides outstanding added value by processing captured shipping data and translate it into core business information.



Elpro

Website: www.elpro.com

ELPRO, founded in 1986, is a leading Swiss manufacturer of innovative monitoring solutions and data loggers for documenting environmental conditions in production facilities, warehouses and the cold chain. We partner with our clients to develop solutions that integrate our high-quality measurement components into their business processes. ELPRO is consistently dedicated to quality, which resonates throughout all facets of our operation – service, technology and customer support. As the inventor of the PDF Logger® we support pharmaceutical and healthcare companies around the world in simplifying their cold chain while having less manual work thus reaching quicker release times.



Marken

Website: www.marken.com

Marken is the leading global clinical supply chain solutions provider dedicated to the pharmaceutical and life sciences industries, supporting over 49,000 investigators in more than 150 countries. Marken integrates Depot and Logistics services into solutions that extend the reach of clinical trials to even the most remote treatment naïve geographies, leveraging decades of experience in the logistics, transport and distribution of temperature sensitive life saving pharmaceuticals, clinical trial supplies and specimen collection. Our team members, technologies and network of facilities bridge the distance between patients and the essential resources of life science companies.



Durbin

Website: www.durbin.co.uk

Summit programme

Durbin combines almost 50 years of heritage with expertise in supplying comparators, standard of care, rescue medication and ancillaries to pharmaceutical companies both directly and via third parties to bring a difference to the market. Durbin prides itself on its sourcing network regularly purchasing from 110 different countries and distributing to over 180. Over nearly 50 years Durbin has built up a global network of wholesalers and specialist suppliers. This network allows effective sourcing from numerous countries in a cost effective and trustworthy way. This is complemented by our heritage of expertise brought about from many years working in and with the regulatory requirements of the clinical trial supply area.



QuickSTAT

Website: <http://quick.aero/quickstat/>

For over 30 years, **QuickSTAT** has played a critical role in managing clinical trial logistics for all phases of research and drug development.

We specialise in global shipping of time and temperature-sensitive clinical research samples, investigational drugs, clinical trial supplies, and dangerous goods.

Our long-standing clients include the leading pharmaceutical, biotech and clinical trial supply companies, CROs and central labs around the world.

Our specialists are available 24/7, delivering complex logistical solutions and expert knowledge for your clinical trials.

QuickSTAT has invested in leading edge, client-centric technology, uniquely designed to support clinical trial logistics.



SanaClis

Website: www.sanaclis.eu

Your reliable partner in CEE region for Monitoring, Warehousing and Logistics services

Monitoring, Warehousing and Logistics services

SanaClis was found in 2000 in Slovakia. SanaClis is the first CRO in Ukraine specialized on IMP management for international clinical studies (since 2001). We are pleased to offer the next services:

Warehousing and Logistics

- Warehousing & Management of IP & CTS (ambient/cold/frozen)
- Distribution IP & CTS:
- own validated shippers for controlled shipments ambient/cold/frozen
- own validated temperature loggers
- Local purchase of study supplies, comparators, rescue medication (corresponding license is available)
- Incineration of IP & CTS
- Customs clearance & brokerage of IP and CTS (including obtaining import/export licenses, certification, metrology attestation).
- SanaClis Inventory Management system (SIMS)
- IP & CTS, building, liability insurance coverage

www.clinicalsupplyeurope.com

Summit programme

Clinical monitoring

- Clinical monitoring of studies with Pharmaceuticals Phase I – IV (Children and Adults)
- Bioavailability and Bioequivalence studies
- Submission and Regulatory Affairs activities
- Site coordination and management: Site identification and initiation, contracting and payments
- Investigators' Meetings arrangements and support
- Quality assurance
- Medical Translations
- Professional Staffing
- ICH-GCP Training

Central laboratory

- Clinical laboratory testing's (for samples delivered from any location)
- Pharmacokinetic analysis of novel drugs at different phases of clinical trials including phase I
- Bioequivalence studies of medicinal products
- Investigation of new pharmacokinetic characteristics of registered medicinal products
- Therapeutic drug monitoring
- Quality control of medicinal products registered in Russian Federation



Clingen Group

Website: www.clinigengroup.com

Clingen Group is a specialty pharmaceutical company headquartered in the UK with offices in the US & Japan. Dedicated to delivering 'the right drug, to the right patient at the right time', Clinigen Group has three operating businesses; Specialty Pharmaceuticals, Global Access Programs and Clinical Trials Supply. Clinigen CTS specialises in sourcing commercial medical products for international clinical studies. These include comparator drugs & non-investigational products such as adjuvant and rescue therapies. Via a global network of audited suppliers and direct-to-innovator relationships, Clinigen supports its customers with secure and cost effective Smart Sourcing™ Solutions.

Pricing and Discounts

End User Packages:

Package Option	Platinum Pass	Gold Pass	Silver Pass	Economy Pass
Register and Pay by 12th September	€ 899	€ 499	€ 399	€ 299
Register and Pay by 17th October	€ 999	€ 599	€ 499	€ 399
Register and Pay by 21st November	€ 1,099	€ 699	€ 599	€ 499
Standard Price	€ 1,199	€ 799	€ 699	€ 599
What's included?				
2 Main Days of the Summit: (22nd & 23rd Jan 2014)	✓	✓	✓	✓
Workshop A: Distribution Practice	✓	✓	✓*	X
Workshop B: Effective Labelling	✓	✓	X	X
Conference presentation: Access to audio recording post event on B2B iQ (www.b2biq.com)	✓	X	X	X

✓* or you may select workshop B instead. Silver pass allows you to select one workshop **A or B**
Please select the one that you are most interested in attending and specify it in your registration form.

A la carte (available for end user packages only)

Workshop A: Distribution Practice	€ 100.00
Workshop B: Effective Labelling	€ 100.00
Conference presentation: Access to audio recording post event on B2B iQ (www.b2biq.com)	€ 599.00

Summit programme

Service and Solution Providers:

Package Option	Platinum Pass	Gold Pass	Silver Pass	Economy Pass
Register and Pay by 12th September	€ 2,999	€ 2,399	€ 2,199	€ 1,999
Register and Pay by 17th October	€ 3,099	€ 2,499	€ 2,299	€ 2,099
Register and Pay by 21st November	€ 3,199	€ 2,599	€ 2,399	€ 2,199
Standard Price	€ 3,299	€ 2,699	€ 2,499	€ 2,299
What's included?				
2 Main Days of the Summit: (22nd & 23rd Jan 2014)	✓	✓	✓	✓
Workshop A: Distribution Practice	✓	✓	✓*	X
Workshop B: Effective Labelling	✓	✓	X	X
Conference presentation:				
Access to audio recording post event on B2B iQ (www.b2biq.com)	✓	X	X	X

✓* or you may select workshop B instead. Silver pass allows you to select one workshop **A or B**
Please select the one that you are most interested in attending and specify it in your registration form.

Please note:

- All 'Early Bird' discounts require payment at time of registration and before the cut-off date in order to receive any discount.
- Any discounts offered (including team discounts) must also require payment at the time of registration.
- All discount offers cannot be combined with any other offer.

Book your space in one of the 3 ways:

Via email: enquire@iqpc.co.uk

Phone: +44 (0)2073689300

Online: www.clinicalsupplyeurope.com

www.clinicalsupplyeurope.com

Summit programme
