	Clinical Trial Supply Midwest **September 12th 2017** **Day One**
07:45	Registration and refreshments
08:25	Chairman's opening remarks
	The first 4 sessions will be plenary with OCT Midwest (held in the OCT presentation room)
08:30	**Discussing the impact the 21st Century Cures Act will have on the US Pharma industry and operating models to plan ahead during political uncertainty** • Key features of the 21st Century Cures Act, particularly changes in the use of Real World Evidence and Summary Data for indication approvals • The impact of the January 2017 "One-in-Two-Out" Executive Order calling for two regulations to be eliminated for every new one issued on the rollout of the 21st Century Cures Act 20 minute spotlight presentation session followed by 10 minutes of Q&A. *Confirmed speaker*: **Amber Meriwether**, JD, MA, Senior Manager, Medical Affairs Lead, Contracts & Outsourcing, Medical and Development - **Astellas Pharma Global Development, Inc.**
09:00	**Trends in Industry Responsiveness to New Innovations for Clinical Trials** • Results from Advanced Clinical's 2017 Industry Innovation Survey, which covers reactions to new innovations in clinical research from industry-wide survey responders • Forecast of future trends in clinical trial technology use based on survey results • Strategies for operationalizing new tools and tech **Julie Ross**, President - **Advanced Clinical**
09:30	**Striking the balance between outsourcing and using in-house resources to improve efficiency in your trial: Which model offers the most value to sponsors?** • Evaluating your internal expertise to decide which processes to outsource ensuring you make the most of in-house capabilities • Advantages and challenges of hybrid vs full outsourcing models to identify which is more suitable for your company • Ensuring you are attracting successful suppliers who will provide clinical and regulatory experts to work with you • Evaluating the risk of either outsourcing model to understand who is ultimately responsible for different aspects of the trial **Barbara Kaesdorf**, Associate Director Clinical Affairs- **Abbott**
10:00	**Exploring multiple vendor management strategies to improve the overall running of your clinical trial** • Leveraging the power of multiple communication methods • Dealing with the "weak link" to improve vendor management across the clinical study • Empowering vendors the manage themselves • Strategies to manage vendors across multiple disciplines **Kenya Barber,** Director, Clinical Operations, **Essa Pharmaceuticals**

10:30	Morning refreshments and networking
11:00	**GMP best practice for Direct to Patients and Virtual Clinical Trials exploring the requirements for delivering drug supply** • Adhering to GMP regulations ensuring standards are covered for delivery of clinical supply • Controlling temperature and shipment integrity in a Direct to Patient setting ensuring regulatory compliance in supply chain • Managing significantly increased costing compared to benefits of reaching wider patient pool for supply to clinical trial • Navigating the logistics of drug delivery without site operation to ensure safety of shipments • Harnessing the commercial benefit of Direct to Patient while navigating the complications brought to drug delivery **David Adams,** Clinical Supplies Lead, **Shire**
11:30	**Bridging the Gap of Clinical Supplies Management** • Analyzing the traditional model, the role of the sponsor and the contract packager • Intro to clinical supply management including managing the drug supply from cradle to grave, clinical trial management and interaction with IRT • Exploring the evolution of the role and relationship transition from one study to managing the compound from the clinical trial perspective and responsibility of the unblinded role • Reviewing case study examples: contingency planning for company attrition and the virtual company model • Looking ahead to future plans and opportunities and how to enhance partnership feedback model with the sponsor **Katy Ostertag-Johnson, MS, PMP,** Sr. Manager, Clinical Supply Chain**, PCI Pharma Services** **Greig J. Ross**, Business Development Executive, **PCI Pharma Services**
12:00	**Meeting the Needs of Any Phase Study Requiring Un-Blinded Medication or Supplies through Pharmacies** • Changing the paradigm of the clinical study procurement and distribution process for medication and supplies • What challenges exist with current clinical supply chain processes and what more can be done to resolve these difficulties? • Exploring alternatives processes for faster and easier study start up, improved flexibility and affordable study management • Examining systems for enhancing subject safety, adherence and retention **Tom Heck,** President, **Rx Solutions**
12:30	Lunch and networking
13:30	**PANEL DISCUSSION** **Making your manufacturing relationship work: Managing problems** • Complete one-stop manufacturing vs contracting for manufacturing, analytical and packaging separately • Ensuring your manufacturer follows SOPs • Obtaining stability data in a timely fashion • Sourcing your API issues with manufacturing outside the US **Tony Giordano,** President and CEO**, ArterioMedix**

	Matthew Galluppi, Manufacturing Manager, **Athersys**
14:15	**Preparing shipments for global locations, outlining best practice and guidelines for international drug supply** • Mapping pathways for shipment process, establishing requirements to avoid supply delays • Establishing IMPD requirements with local authorities, best practice communications for clinical supply • Implementing system integration to ensure oversight of clinical trial supply during shipment • Forecasting for shipping requirements post clinical study, establishing requirements to return excess supply **Beth Smith**, Manager, Clinical Supply Chain, **Melinta Therapeutics**
14:45	Afternoon refreshments and networking
15:15	**Forecasting costs and effectively managing budgets exploring accurate methods of predicting trial supply expense** • Establishing best practice to track clinical payments to sites managing payment strategy when operating multiple timelines • Assessing billing corrections when trials overrun and how to manage the impact this has on forecasted costs of supply • Establishing best practice for tracking work hours at clinical sites, monitoring study hours to ensure accurate spending • Exploring the value of forecasting systems in comparison to manual data entry, is this the cost efficient option for clinical supply **Heather Hermann**, Research Compliance Officer, **OSF HealthCare** & **Kellie Bodeker**, Regulatory Manager, **University of Iowa**
15:45	**Comparing and contrasting the risk and benefits involved with in-house sourcing VS out sourcing processes for supply** • Exploring the benefit of internal production for higher accountability and control of supply production • Managing vendor relationships with clear communication to reduce manufacturing delays • Creating strong relationships and constructive planning tools to ensure achievable timelines within supply • Justifying costing and control of in-house VS out-sourcing and ensuring transparency for unique clinical requirements • Guaranteeing ROI and operational excellence when externally sourcing drug manufacturing **Jenny Skyrm,** Clinical Quality Manager**, Merz North America**
16:15	**Chairman's summation and close of conference**
16:25	**Drinks Reception**

	Clinical Trial Supply Mid West **September 13th 2017** **Day Two**

08:15	Registration and refreshments
08:50	Chairman's opening remarks
09:00	**Navigating the path of new drug development in China: Experience of a small US biotech company** • Understanding China's laws and regulations from an outside perspective as the market emerges to compete with US, EU and Japan • Navigating partner relationships to join the emerging market and understand compliance before embarking on a clinical trial • Ensuing preparation with regulations for API to travel through customs without delays **Ruth Wu-Wang**, CSO, **Vidasym**
09:30	**Excess Stock: Forecasting/modeling… what's next?** Potential solutions to minimize destruction of usable comparators and standard of care drugs, covering procurement and charitable donation A practical guide on how to procure cost efficient sustainable procurement for clinical trials • Procurement Strategies • Storage Strategies • Excess Stock Solutions **Todd Galles**, Business Development Principal, **DURBIN**
10:00	**Establishing criticality of vendor oversight and exploring ICHE6 Revision 2 ensuring transparency throughout supply manufacturing** • Incorporating performance and quality metrics to ensure effective oversight of supply development • Implementing routine monitoring in vendor relationships to improve forecasting accuracy of supply • Appreciating partnerships and the benefits of effective oversight for clinical supply timeline efficiency • Establishing methods to implement revised regulations of ICHE6 and aligning partner interests to ensure efficient supply • Reviewing documentation for efficient monitoring and assuring quality to regulatory standards for clinical supply **Seng Dao VanMany,** Clinical Project Manager
10:30	**Industry Survey Results: Assessing the Current and Future State of Clinical Trial Supplies** **Brian Keese,** PCI Pharma Services and Vishal Khushalani, **Sonoco ThermoSafe**
10:45	Morning refreshments and networking
11:15	**Emphasizing the Last Leg of clinical trial supply highlighting the importance of drug destruction for NDA's** • Encouraging site engagement continues post study ensuing effective data collection to meet NDA requirements of supply pathway • Implementing destruction into forecasting activities to ensure accountability for supply in the last leg of trials • Navigating the challenge of drug destruction at global sites for international clinical sites with excess supply • Exploring electronic information collection for Trial Master Files increasing oversight for clinical supply **Wendy Perez,** Director of Clinical Operations, **Endocyte, Inc.**
11:45	

	Exploring your clinical trial imports and exports to ensure a smooth transition through US Customs • Demystifying the import/export regulations to increase uniformity of practices across ports of entry ensuring a timely resolution of nationwide trade compliance issues • Pinpointing the goals and achievements of the centre to date to prevent a holdup at Customs of your clinical supplies • Utilizing the Centers' recent expansion to include processing for the entire industry to appreciate the effect on your clinical supply • Reviewing key strategies for ensuring your drugs make it through customs in a safe and timely manner **Nancy L. Anderson,** Pharmaceuticals, Health and Chemicals CEE, **United States Customs and Border Protection (US CBP)**
12:15	Lunch and networking
13:30	**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. Each roundtable session lasts for 45 minutes, and delegates may attend up to 2 roundtables
Roundtable 1	**Comparatively exploring commercial VS clinical supply chain; lessons learnt for trial supply** **Shan Rahman**, Director, Global Project Management, **Takeda Pharmaceuticals**
Roundtable 2	**Discussing partner relationships to join the emerging market before embarking on a clinical trial: exploring US FDA vs cFDA; the recent cFDA regulatory changes; having a partner in China; exploring the option of co-developing a new drug with a partner in China** **Ruth Wu-Wong**, CSO, **Vidasym**
Roundtable 3	**Immunotherapy, Steps Required to Obtain FDA Approval for Cancer Therapy** **Edward Cohen,** Professor Microbiology and Immunology**, University of Illinois College of Medicine**
Roundtable 4	**Exploring how companies are addressing the QRM in ICH E6 Addendum- with regards to outsourcing and working with CROs** **Joseph F. Gotowko**, Assistant Director, R&D Quality System, **Abbvie**
Roundtable 5	**Overcoming hurdles presented when outsourcing clinical trials off-shore** **Minji Bae**, Assistant Director, Clinical Vendor Management, **Abbvie**
15:00	Chairman's summation and close of conference