

FOCUS DAY**20th February 2012****Identifying and countering the challenges associated with supplying trials in new and emerging global markets**

08:30	Registration and refreshments
09:00	Chairman's opening remarks Erik Meyer, PhD; Associate Director International Clinical Trial Supply; Merck Serono
09:20	Developing a synchronised supply chain by analysing the global company model versus international company model and determine the model that will be most cost-effective <ul style="list-style-type: none"> • Considering the costs and benefits of becoming a global organisation to reduce costs and improve communication • Assessing the benefits of centralised supply chain over a decentralised system that will build strategic alliances and optimise communication • Determining the weaknesses in a centralised supply chain relative to a decentralised system in regards to drug approval delays and security and the best ways to minimise the effects • Overcoming the difficulties of restructuring the regional supply chains to a single global supply chain to prevent unexpected delays and costs • Finding practices that can ensure the global supply chain can cater to demands of individual countries and improve efficiency • Uncovering optimal methods to synchronise regional offices in different business climates and determining key strategies for implementing it • Integrating communication platforms across the company to ensure effective transfer of information to improve visibility in both developed and emerging markets Helena Pavicic, Clinical Trial Supply Manager, Allergan
10:00	China: Clarifying status with legislation in order to efficiently run clinical trials with minimal delay to product approval <ul style="list-style-type: none"> • Discovering the unique working culture - appreciating Chinese business culture in order to ensure good communication with trade companies and regulatory bodies. • Investigating the Chinese legislation of clinical trials and manufacturing protocols to ensure product approval • Forecasting drug approval timelines and effectively preparing the manufacturing pipeline to prevent overruns • Evaluating the management of trials and transport across different climates to enable successful trials and speedy product launches • Building networks with trade organisations, the government, health authorities and local service providers that will reduce hitches in clinical trial supply chain • Enhancing and maintaining the business relationships in China that will ensure long-term successes in clinical trial approval processes • Summarising the key strategies necessary to obtain timely product approvals to implement trials effectively Erik Meyer, PhD; Associate Director International Clinical Trial Supply; Merck Serono

10:30	<p>Ensuring effective management of the supply chain to achieve smooth logistics and avoid delays to product launches in Latin America</p> <ul style="list-style-type: none"> • Outlining the complex environment of countries across Latin America and analysing the different country infrastructures that may impact the supply chain procedure • Considering the impact of a poor regional economic infrastructure that contributes towards delays in the supply chain in Latin America and determining the best methods to deal with the delays • Looking into the effect of the logistical demands in Latin America and anticipating how the demands can be overcome in a cost-effective and speedy manner • Reflecting on lessons learned from operating the supply chain in Latin America based on the experiences at Sanofi-Aventis • Creating successful tailor-made supply chain processes for individual countries in a cost-effective manner • Developing and implementing a supply chain that is flexible and can be adapted to unforeseen emergencies in a timely manner <p>Stefan Roehr, Senior Director Supply Chain and Plant Logistics Latin America, Sanofi-Aventis</p>
11:00	Morning refreshments and networking
11:30	<p>Panel Session: Tackling cultural and regulatory differences that will enable timely clinical trials and reduce prolonged delays</p> <ul style="list-style-type: none"> • Assessing the documentation requirements and regulations in place in various new markets to prevent your trial from being subject to delay • Analysing the potential for moving R&D into emerging markets to reduce costs and increase patient pools for clinical trials • Anticipating and avoiding product quality deterioration and drug expirations while awaiting approval and minimising costs of manufacturing additional supplies • Investigating the potential of building a drug regulations database that will enable access to regulatory information upfront prior to trial planning and initiation • Outsourcing the supply chain to local service providers to avoid communication and cultural barriers • Tackling issues with customs: uncovering important formalities and cultural differences that may impact trial outcomes <p>Panel members include: Bernd Schaden, Clinical Supply Chain Manager, Baxter Innovations</p>
12:15	Lunch and Networking
13:30	<p style="text-align: center;">Interactive Roundtables</p> <p>Delegates and speakers will have a fantastic opportunity to discuss two major topics associated with supplying trials in various global regions. This time will allow attendees to share experiences, identify best practices, and learn tips and tricks for your global trials. Along with getting in-depth insight into your major operational challenges, this session is an exciting, interactive way to build your personal network and learn from the experience and expertise of others.</p> <p>Each roundtable session lasts for 30 minutes and registered delegates may attend both</p> <p>Roundtable 1: Identifying the best means of forecasting drug demand in 'low visibility' countries</p>

	<p>Bernd Schaden, Clinical Supply Chain Manager, Baxter Innovations</p> <p>Roundtable 2: Defining strategies to design a smooth manufacturing pipeline in emerging countries</p>
14:00	<p>Identifying security procedures that will ensure secure delivery of goods and maintain stock by minimising theft in emerging markets</p> <ul style="list-style-type: none"> • Outlining challenges of ensuring the security of trial supplies during transport to emerging markets • Obtaining local knowledge about the value of the drugs on the black market to assess your vulnerability in specific regions • Considering the best methods of transporting goods to and within vulnerable regions that will minimise product loss • Assessing the potential cost impact of securing drug supplies to high-risk regions and develop safe and cost-effective strategies • Identifying key technologies to track and trace drug supplies to the target location to ensure the safety of the trial supplies • Developing safe and secure transporting methodologies through partnerships with local service providers that will help transportation through vulnerable regions • Building coalitions with competing pharmaceutical companies to improve the security of drug products across the region <p>Cathy Brown, Process Improvement Manager – Security Operations Group, Mundipharma Research Ltd.</p>
14:30	<p>Maintaining and monitoring drug supplies in transit to ensure drug quality and prevent wastage due to poor storage during distribution</p> <ul style="list-style-type: none"> • Highlighting the current concerns with ensuring quality control that lead to product spoilage in emerging markets that can increase cost margins • Evaluating temperature maintenance during import and export of goods to emerging markets to avoid product spoilage • Considering the costs of removing spoiled products from depots and identifying the best methods of destroying spoiled drugs in emerging markets • Determining if the products are 'suitable' for use and finding guidelines for quality assessment in extreme climates • Weighing the benefits of investing in active storage solutions instead of passive solutions during the transportation of drugs to ensure product quality • Optimising drug storage conditions through passive or active solutions, particularly in less developed regions in order to maintain the effectiveness of the drugs • Enhancing the monitoring and auditing of drug storage conditions at depots and during transport to guarantee the drug supplies are viable for clinical trials and product launch <p>Sophia Mitchell, Clinical Supplies Projects Manager, Mundipharma Research Ltd.</p>
15:00	<p>Chairman's summation and close of focus day</p> <p>Erik Meyer, PhD; Associate Director International Clinical Trial Supply; Merck Serono</p>