Pharma Forum

Pharma trifft Medizintechnik

Curricula Vitae der Referenten

Anke Liewald

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Anke Liewald started in January as Global Head of CMC Project Leaders for Large Biomolecules (Regeneron) She was Head of Global Drug Device Combination Project Management and Site Frankfurt Coordinator and responsible for providing leadership for the portfolio of sanofi medical devices under late stage development. She is coordinating of all Frankfurt site hub communication and strategic site integration and plans. Prior to that she was Head of Usability and Risk Management in Global Medical Devices, responsible in this position for the compliant development of medical devices and combined products within Sanofi globally. She has worked in the pharmaceutical industry for 25 years, starting in the development of new drug products focusing on characterisation of new chemical entities. mid-2000 she took over responsibility for internal as well as supplier quality inspections in the field of active ingredient production and drug product production focusing on aseptic filling. In October 2004 she was the appointed Quality Manager for SoloStar ®, the first subcutaneous insulin pen system development project within Sanofi the product launch happened end 2006. Between 2005 and March 2009 she headed the group of Quality Management Products & Components of the newly created pen production site and was responsible as such for external pen components suppliers. Anke moved in April 2009 to the recently created global organisation Global Medical Devices and founded in April 2010 a new group focusing on patient centric needs and being responsible for providing strategic direction for the analysis of the competitive medical device landscape in order to proactively drive operational, tactical, and strategic business decisions and innovation at Sanofi in franchises where medical devices/combined products (pens, auto-injectors, safety syringes, etc..) are an integral part of the business. Anke acquired over the years and during many meetings with FDA (CDRH) a deep understanding and experience of the new FDA regulations for Human Factors Engineering in cooperation with Risk Management and established in the Sanofi Medical Device business a new group integrating Human Factor Engineering and Risk Management. In March 2010 she established a globally coordinated process for Clinical Evaluation for medical devices handling in a consistent way during all development phases of new devices.

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