LUNCH AND LEARN
HEALTH SCIENCES' INDUSTRY UPDATES

13 NOVEMBER 2019 | 11am – 3pm

Come along to this FREE event to meet our experts and to learn more about the new requirements and changes in the healthcare sector. Free lunch will be provided as well as a series of 30-minute presentations from our NSF experts in Germany, the UK and US.

US FDA REGULATORY AND CLINICAL STRATEGIES FOR SUCCESSFUL COMPANION DIAGNOSTICS DEVELOPMENT:

All drugs or biologics that are co-developed with an in vitro companion diagnostic must consider all regulations that pertain to both drugs/biologics and devices.

Kazem Kazempour will examine the background and steps necessary to work with the US FDA for the co-development of such drugs/biologics and their IVD companion.

CLINICAL EVALUATION AND CLINICAL INVESTIGATION FOR MEDICAL DEVICES:

Are your clinical evaluations up to date? Do you know the different regulatory requirements in the European market for clinical investigations? Sandra Bugler will provide an overview of the challenges in the clinical affairs sector.

Sandra Bugler is the managing consultant for clinical affairs at NSF PROSYSTEM GmbH. In her role she has established a team of clinical affairs specialists.

VENDOR MANAGEMENT – HOW TO ACHIEVE COST EFFECTIVE CLINICAL OPERATIONS:

The biggest challenge for biotechnology and medical device SMEs is to undertake their clinical research programmes in a cost-effective manner and maintain the regulatory need for project oversight and control as required by ICH 6R2. This presentation will examine the issues and offer practical suggestions and solutions.

John Shillingford has held senior positions in management, clinical operations and project management for Aptiv Solutions, Averion International (a medical device research company), PRA International and Imform GmbH. He is currently a Director for Amarex Europe.

DEVELOPING A CONTAMINATION CONTROL STRATEGY, AS REQUIRED BY ANNEX 1:

Lynne Byers will talk about the requirement to have a contamination control strategy for sterile products, as this is becoming of increased importance with the draft of annex 1 to the EU GMP Guide.

Lynne Byers is an Executive Director at NSF. She has over 35 years' of pharmaceutical manufacturing management and QA experience working for three major international pharmaceutical manufacturers. In addition, she worked as Head of Inspectorate and Licensing for the MHRA from 2004-2006.

The participation is free and includes the seminar documents, meals and the participation certificate. There will also be an opportunity to network and exchange experiences with other participants and our experts.

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