COMMUNITY REPORT

Devices and Diagnostics Community: Our Time Has Come

Kerri-Anne Mallet

As healthcare technology continues to evolve globally, medical devices are having a profound influence on the pharmaceutical industry. Medical devices and *in vitro* diagnostics are finding commercial and medical success by "pairing up" with different pharmaceuticals and biotechnology products.

For example, personalized medicine is improving chemotherapy outcomes by pairing diagnostics and pharmaceuticals, drug delivery combination products are facilitating patient compliance through unique delivery methodologies, and digital health platforms that allow for patient monitoring are increasingly being used in clinical trials.

At a time when the healthcare industry is experiencing unprecedented convergence, pharmaceutical organizations will benefit from understanding the development processes and regulatory systems governing devices and diagnostics.

Who are we?

Members of DIA's Devices and Diagnostics Community are professionals from all sectors of the healthcare industry with an interest in furthering our understanding of devices and diagnostics. As a community, our mission is to foster collaboration with the global DIA ecosystem and increase awareness of the intersections among medical devices, *in vitro* diagnostics, and chemical and biological drugs.

How do we contribute to DIA?

Dealing with devices can be a distinctive challenge for members of the pharmaceutical community because of the different regulatory requirements and technical components. However, effective educational resources and collaboration between colleagues will make success possible. The Devices and Diagnostics Community intends to be a resource for all DIA members, for those who are already familiar with devices and diagnostics as well as those new to the field.

Our community primarily focuses on education and networking. As we build our community and continue to grow, we will be hosting webinars and presentations on cutting-edge topics affecting devices and diagnostics as well as thought-provoking discussions about the opportunities and challenges that devices and diagnostics present to the pharmaceutical industry. Our events will allow members to expand their understanding while facilitating idea-sharing and collaboration. In the long term, the community will also contribute to publications and facilitate advocacy surrounding the development of medical device and diagnostic requirements.

How can I participate?

Start by going to the DIA website and sign up to be a member of our Community. This will allow you to participate in discussions on our Message Boards and get feedback from your colleagues. Alternatively, attend one of our educational or networking events. For those interested in taking on a greater role, contact one of our core team members about leadership opportunities within the Community.

We also want to hear your own ideas for events, goals for the community, or opportunities for collaboration. Whatever your interest, please send us your feedback.

The line between pharmaceuticals and devices is fading with each new technological advancement but collaboration will drive success for organizations, professionals and patients. Join the Devices and Diagnostics Community today to tap into our network of talented professionals, dedicated to sharing knowledge and supporting all sectors of the industry!

Core Team

Community Chair Kerri-Anne Mallet is Vice President of Clinical & Regulatory Affairs at Pharmatech Associates, a full service life science consulting firm. She also serves as an Advisory Board Member for Summit Street Medical, LLC, an early stage drug delivery device company focused on providing solutions for unmet needs at the intersection of sports and healthcare technology. Kerri has been in the biotechnology/medical device industry for more than two decade, and has been instrumental in the successful application of various regulatory submissions worldwide. Her experience includes medical devices, combination products, IVDs, and biologically derived materials.

Program Coordinator Darin S. Oppenheimer is an Executive Director of the Drug Device Center of Excellence focusing on Medical Devices and Combination products at Merck. Darin is involved in many facets of the Product Development Lifecycle including regulatory submissions and due diligence, and participates in industry trade organizations and standards committees. His prior background as an R&D scientist focused on pharmaceuticals and medical device diagnostic applications for biomarker and drug discovery.

Communications Kristiina Rosin is a Regulatory Policy and Intelligence Analyst at AbbVie (UK). Kristiina is involved in identifying and analyzing new regulatory intelligence for Europe, Middle East and Africa, and also leads the medical device and labelling regulatory policy topics. Her interest primarily lies in the EU. Kristiina is also involved in the in-vitro diagnostics subgroup of the EBE-EFPIA Personalised Medicines Priority Working Group and the Safety Labelling subgroup of the EFPIA Middle East Regulatory Network.

Education Coordinator Fatima Hasan is Assistant Manager-Medical Writing at APCER LS. She works on regulatory documents for major pharmaceutical companies. She has worked on medical devices, and in-vitro diagnostics. As Education Coordinator, she is interested in enhancing our community's knowledge base by reaching out to other community members and increasing interactions with specialists within the community.

BACK TO ISSUE