CROSS-INDUSTRY *Organizations*

An IPAC-RS update: A practitioner's perspective on human factors

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Evidenced by the growing numbers of conference presentations, the 2011 United States Food and Drug Administration (FDA) Draft Guidance and the 28 public submissions on the Draft Guidance, human factors engineering (HFE) and usability engineering (UE) –which focus on "understanding and optimizing how people interact with technology"–are areas of growing interest to device developers and regulatory authorities. (June 2011 FDA Draft Guidance "Applying Human Factors and Usability Engineering to Optimize Medical Device Design.") To help unravel the ways human factors and handling studies are integrated into device design, as well as current regulatory expectations, the IPAC-RS Device Working Group recently held a public webinar on human factors, "A practitioner's perspective on HF as part of OINDP development."

This webinar contributed to the Device Working Group's objectives of understanding and promoting best practices for OINDP device design. In the past, the Working Group has organized sessions and presentations for the IPAC-RS 2008 and 2011 conferences, helped coordinate the IPAC-RS response to the FDA Draft Guidance on human factors in 2011 and contributed to the IPAC-RS patient concordance initiative. "A practitioner's perspective" provided an opportunity for the IPAC-RS Working Group to connect with a diverse audience around the globe.

Over the course of an hour, this webinar provided an introduction to human factors and the growth of interest in the topic. Julian Dixon, the IPAC-RS Science Advisor who gave the presentation, explained the potential that HFE has to manage use-related risk and the ways recent events have focused regulatory attention on the topic. He delved into best practices for integrating HF into device development, both in terms of the objective and the process, discussed regulatory practice in the European Union compared to the United States and reviewed the FDA Draft Guidance.

Mr. Dixon also offered perspectives on pitfalls and opportunities from the viewpoint of a practitioner. Inadvertently labeling non-critical use errors as critical, confusing HF with traditional marketing and clinical studies as well as lack of preparation for HF studies were among several common pitfalls. Suggested opportunities included better designs through thorough adoption of HF, cross-industry work to improve the effectiveness of instructions for use (IFUs) and clarification of HF expectations for OINDPs.

Participants were able to submit questions throughout the webinar, a selection of which were answered during a Q&A session at the end of the presentation. These focused on characteristics of user groups selected for inclusion in studies and HF studies for generic devices.

A recording of the webinar and more information about the IPAC-RS Device Working Group are available on the IPAC-RS website: www.ipacrs.com/Device.html.

Upcoming IPAC-RS Webinar Opportunities

OINDP Materials

The International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) OINDP Materials Working Group is continuing its webinar series addressing aspects of materials quality and their publicly available Baseline Requirements for Materials used in Orally Inhaled and Nasal Drug Products (OINDP). Upcoming sessions include:

October 11: Strategies for Developing Acceptance Criteria

November 15: Change Management

These webinars will provide key information on concepts and approaches that are critical to effective extractables and leachables evaluation and materials quality management.

Visit **www.ipacrs.com/Materials.html** for updates and registration information.