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BRANDNEWS

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DSI DrugSafetyInstitute
A Subsidiary of Brand Institute

DSI offers new service for HUMAN FACTORS STUDIES for Combination Drug/Device product design & development

In accordance with FDA's February 2016 Draft Guidance titled "Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development", combination products (e.g. Insulin/Pen devices, respiratory drug/devices, drug/syringe, etc) and their labeling should be exposed to Human Factor Studies in order to maximize the likelihood that the user interface is safe and effective. With the recent DSI hiring of Carol Holquist (former Director of DMEPA) we are proud to offer her expertise in the area of Human Factors and medication error prevention, along with expertise from Jerry Phillips (former Director of DMEPA) and Nora Roselle (former Team Lead in DMEPA). For purposes of our services, this will include drug and drug/device combinations in an IND, NDA, BLA and ANDA.

The following consulting services are now available:

1. Review of Product Design, Container Labels and Carton Labeling to Minimize Medication Errors
2. Critical Task Identification
3. Review of Human Factors Formative Study Results for advice on product design or labeling changes
4. Protocol Review of Human Factors Simulated-Use Validation Study before submission to FDA
5. Assistance with comparative task analysis for ANDAs
6. Assistance with Root Cause Analysis of Actual or Potential Medication Errors

Carol Holquist, R.Ph.

Vice President Global Naming, Labeling & Human Factors, Drug Safety Institute

Former Deputy Director of the Office of Regulatory Operations in the Office of Generic Drugs at the Food and Drug Administration (FDA), Center for Drug Evaluation & Research (CDER); and former Director of the Division of Medication Error Prevention and Analysis (DMEPA)

For more information, please contact your local Brand Institute Account Team:

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