The 10th International ENBIS Conference
Antwerp, Belgium
12-16 September 2010.

The ENBIS Design of Experiments Special Interest Group Session at ENBIS10

The ENBIS DOE SIG is planning to sponsor a special session at ENBIS10 in Antwerpen.

The session will consist of 3 invited speakers who will set up the stage for a SIG meeting open to all ENBIS membership.

The theme for the SIG meeting will be ***Quality by Design (QbD) applications in the pharmaceutical industry***. The session will be also open to other topics, depending on the interest of the participants.

Some background to QbD:
Recently, the Food and Drug Administration (FDA) and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use launched a **Quality by Design** initiative (ICH, 2005). It encourages new drug applications to include a **Design Space** and risk based control strategies. The basic idea is that drug product developers should study the behavior of **Critical Quality Attributes** in their proposed new products, under variations in the raw material and process control parameters. This area of application is beyond the traditional role of Biostatisticians in clinical trials (see ICH, 2005, Nasr, 2009, Kenett and Kenett, 2008, Kenett, 2009 and Peterson et al, 2009). Moreover, the application of simulation experiments, Bayesian adaptive designs and data mining techniques in the critical path of research investigating efficacy and safety of new drug products is also encouraged by the FDA. These recent developments have created new opportunities for Statisticians who can now play a key role throughout the life cycle of drug development and contribute actively to the discovery process, for the benefit of companies and society in general. In the DOE SIG meeting we plan to discuss the essential elements of Quality by Design and map out several opportunities for Statisticians to contribute actively in this framework.

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- Kenett, R.S., "By Design", *Six Sigma Forum Magazine*, pp. 27-29, November 2009.
- Nasr, M., "Status and Implementation of ICH Q8, Q9, and Q10 Quality Guidelines: Topic Introduction and FDA Perspective", Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting, Rockville, MD, August 5, 2009
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