



Workshop | 21st September 2010, 16.00 until 19.00 h

BioCampus Cologne
Konferenzzentrum
Hochhaus, 11. Etage
Nattermannallee 1
50859 Köln

- ▶ **Good Clinical Practice – High Importance Specifically For Small Biotech Companies; You Cannot Afford Rejections**
 - ICH & GCP: Background & their global coverage
 - Key aspects of ICH & GCP
 - Impact, challenges & opportunities for biotech companies
 - What authorities really want - findings from inspections and strategies to prevent trouble

Dr. med. Edgar Fenzi
Managing Director, FGK Clinical Research GmbH

- ▶ **First in human studies: Which data package is required preclinically? What do authorities in Europe and in North America expect?**
 - Proof of concept studies in animals and how they are seen by regulators
 - Toxicology: is ICH always sufficient? Which species is “relevant”
 - The role of ex-vivo data for biologicals

Dr. Monika Chabicovsky / Dr. Stefan Blesse
Senior Consultants, Granzer Regulatory Consulting & Services

For further information and registration please contact:

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The workshop will be moderated by key speakers from the companies below:

FGK Clinical Research GmbH is a Europe-based full service Contract Research Organization offering the complete range of clinical development and consulting services to pharmaceutical, biotechnology, and medical device companies. FGK headquarters are in Munich, with more than 60 highly-skilled and experienced employees working on local and global projects, covering clinical studies Phases I to IV and post-marketing studies. In addition, FGK has subsidiaries in the UK and Czech Republic, and further subsidiaries are planned. FGK has extensive experience in all major therapeutic areas and clinical research fields allowing it to effectively design, manage, and analyze development programs and clinical trials.

At Granzer Regulatory Consulting & Services, we provide strategic and operational input for drug and device development and all elements of regulatory affairs, including a sound development and regulatory strategy. We start by defining the right time for the first contact with the relevant regulatory authorities in Europe and the United States. We facilitate the first contacts, help prepare briefing packages for authority meetings and accompany all phases of interaction, including dossier preparation and full regulatory submissions. We track applications, facilitate, prepare and moderate authority meetings in national, mutual recognition including arbitrations, referrals and centralized procedures. We also provide the right support for filings and contacts with the FDA.

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