

Die Vortragsthemen:

New scientific and Regulatory Approaches for Flexible Design of Early Trials and their Preclinical Support

- New guidelines: Tailored early clinical trials and supportive toxicology programs: microdose, pharmacologically active or tolerability dose.
- Review on ICH M3 2009 and ICH S9 2009 guidelines and EU Innovative Medicine Think Tank group
- Inclusion of women of childbearing potential during early state development
- Risk mitigation and safe start dose for different drugs
- Approaches for oncology drugs, biologics and small molecules

Overview on Approaches for Scientific Advice and Regulatory Consultation in the EU

- Scientific Advice Meeting: Purpose, Timing, Necessity
- Scientific discussions with regulators during development

Overview on Approaches for Meetings with the Food and Drug Administration and Fast Track regulation in the US

- FDA Meeting: Purpose, Timing, Necessity
- Use of Fast Track regulations in the US

Designing Safe and Efficient Phase I Studies

- Formulation issues, GMP and kinetics
- Phase I study design: population, sample size, starting dose, dose-escalation scheme, etc.
- How to optimize design of first-in-human studies and make your Phase I program more efficient

Arriving to the Clinical Side: Trial Design considerations

- Approaches for taking new products into human trials
- Preclinical data, immunogenicity and PK/PD
- Design of clinical program and follow up

Einladung zum Workshop

am 11. Februar 2010

13.30 – 17.30h

Austria Wirtschaftsservice GmbH

Ungargasse 37

1030 Wien

**“Crossing the Bridge from
Preclinical to Clinical Studies -
Fast Track Approaches to Concept Testing
& Market Authorisation”**

Bengt R. Danielsson

Franz Buchholzer

Gregory M. Hockel

Mario Tanquay

Jeff Freitag

PharmaNet Development Group

Gerne möchten wir Sie vorab zum Lunch
ab 12.30h einladen!

Die TeilnehmerInnenzahl ist auf 18 Personen limitiert!

Um Anmeldung unter office@lisavr.at bis
spätestens 4. Februar 2010 wird gebeten.