

Invitation

to the symposium

„Pharmaceutical
Stability Testing according
to ICH Guidelines,
FDA and GAMP“

on 20th May 2008
in Hillerød



Vötsch Industrietechnik GmbH
Umweltsimulation · Wärmetechnik

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Symposium

You should not miss this appointment!

On 20th of May 2008, Vötsch Industrietechnik GmbH stages a customer symposium with the title: „**Pharmaceutical Stability Testing according to ICH Guidelines**“ at Hotel Pharmakon (www.pharmakon.dk) in Hillerød, 30 km north of Copenhagen.

We would like to invite you - free of cost - to this event. We are proud to announce this event's **guest speaker; Dr. Stefan Schmitz** who brings along 15 years of experience in leading positions in the pharmaceutical industry. For more information about the activities of Dr. Schmitz, please visit his website: www.cmc-pharma.de

Apart from interesting presentations, there will be enough time for detailed discussions and your feedback is highly valued. We will also present a selection of our test systems and solutions. During your stay, we will care for your well-being, serving you lunch and coffee, still at **no charge**.

All participants will **receive a certificate**.

Please confirm your binding participation by sending us an e-mail at the address: sympos@beatronic.com no later than the **1st of May 2008**. Send us your business card, an Outlook "vCARD" or an e-mail with the following information: Company, name, phone no. and e-mail address.

Please note, **seats are limited** and booking is binding.

For any queries please contact from Beatronic Supply, Mr. Steen Lauritzen (telephone: +45 4824 0220 or e-mail: lauritzen@beatronic.com)

We look forward to your participation.

With best regards

Beatronic Supply
Steen Lauritzen
Managing Director

Vötsch Industrietechnik GmbH
Michael Holzwarth
Product Manager Pharma

Program

- 9.00 h** **Arrival at Pharmakon**
Milnersvej 42 - 3400 Hillerød
- 9.15 h** **Welcome and association**
By Mr. Steen Lauritzen, Beatronic Supply
- 9.30 h** **Company presentation**
Introduction of Dr. Stefan Schmitz, CMC Pharma
By Mr. Michael Holzwarth, Vötsch Industrietechnik
- 9.45 h** **Modern Stability Testing**
for Biotech and Pharmaceutical Companies
(Regulatory Compliance and ICH Framework)
By Dr. Stefan Schmitz, CMC Pharma
- 10.30 h** **Coffee break**
- 11.00 h** **Qualification acc. to GAMP5**
News/Changes compared to GAMP4
By Dr. Stefan Schmitz, CMC Pharma
- 11.30 h** **Effective qualification**
with the example of a Stability Test chamber
By Mr. Michael Holzwarth, Vötsch Industrietechnik
- 12.00 h** **Stability Test equipment**
Trends and possibilities of automation using modern stability test equipment
By Mr. Michael Holzwarth, Vötsch Industrietechnik
- 12.30 h** **Lunch**
- 13.15 h** **21 CFR Part 11**
Background and Demands
By Dr. Stefan Schmitz, CMC Pharma
- 13.45 h** **21 CFR Part 11 in Practice**
Sample Management, Recording and electronic signatures
By Mr. Michael Holzwarth, Vötsch Industrietechnik
- 14.30 h** **Coffee break**
- 15.00 h** **Open discussion/evaluation**
Issuing of participant certificates
- 16.00 h** **Departure**