Donawa Lifescience Consulting

Certificate of Training

This is to confirm that

Helmut Schweiger

has participated in
the Medical Device One-Day Seminar, at
Hotel Königshof, Karlsplatz 25, 80335 Munich, Germany

on 7 November 2011

**"European Device Clinical Studies:
Best Practices for Successful Planning and Conduct"**

This training included presentations and interactive discussions on :

- EU and US regulatory framework for device studies
- Analysis of revised EN-ISO 14155:2011
- Key aspects of device clinical research, EU vs US
- The journey from study design to successful clinical report:
  - Protocol development
  - Site/country selection and successful patient enrolment
  - Ethics Committee and Competent Authority submissions
  - Study monitoring, safety reporting, complaint handling

Lecturers:
Daniela Karrer, Director, Clinical Affairs
Donawa Lifescience Consulting

Tami Abudi, Senior Associate, Clinical Affairs
Donawa Lifescience Consulting

Ulrike Burkhardt, Clinical Project Manager
Donawa Lifescience Consulting

7/Nov/2011

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(date)