Donawa
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Certificate of Training

This is to confirm that

Helmut Schweiger
Consultant Senior CRA

has participated in
the Clinical Department Internal Meeting at
Donawa Lifescience Consulting,
Piazza Albania 10, 00153 Rome, Italy

on 10 September 2013

This meeting included presentations and interactive discussions on :

- Preparing for an FDA inspection
- In vitro diagnostics (IVDs): overview of EU and US regulations
- Clinical Studies under the new Medical Devices Regulation – what do we know so far?
- Overview of the FDA Guidance document "Oversight of Clinical Investigations – a Risk-based Approach to Monitoring", August 2013
- Lessons learned from our current studies – feedback and open discussion

Lecturers:
Maria E. Donawa, President
Donawa Lifescience Consulting

Roger Gray, VP, Quality and Regulatory
Donawa Lifescience Consulting

Carlo d'Alessandro, Director, IVD Quality and Regulatory
Donawa Lifescience Consulting

Matteo Mosso, Clinical Project Manager,
Donawa Lifescience Consulting

Daniela Karrer, Director, Clinical Affairs
Donawa Lifescience Consulting

Maria E. Donawa 10 Sep 2013

Maria E. Donawa, President (date)
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