

## Audit Certificate

We hereby confirm that

Dr. Ebeling & Assoc. GmbH  
Rütersbarg 46, 22529 Hamburg

was audited on 14 November 2007

by representatives of the Steering Committee of the BAH-WiDi  
"Joint Preparation of (parts of) PSURs"

The following issues were audited:

- Organisation and general situation
- General questions on quality assurance
- Client management
- System validation
- Access to the system
- Performance in the project
- Trainings
- Testplans and standards
- Change control / configuration management

Based on the results of the audit the auditors assume that the overall system is principally valid to fulfill the tasks determined by contract in a quality-controlled and –assured manner.



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Dr. Elmar Kroth  
Head of Pharmacovigilance of BAH,  
Lead Auditor

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19 February 2009

date