

URS, RfP and SOP authoring

- Preparation of User Requirement Specification (URS)
- Preparation of Request for Proposal (RfP)
- Preparation of SOPs prior to system implementation

GxP Computerised Systems Validation (CSV)

- Upgrading or implementing systems in a manner ensuring that today's GxP standards are used and documented
- Tutoring and sparring
- Preparation of IQ, OQ and PQ documentation
- Preparation of overall Validation Plan, test cases, test scripts
- Providing resources for test execution and coordination
- Preparation of Validation Summary Reports

Computerised System Audits

- Development of sound concepts of due intelligence before (or after) major upgrades or implementation of a new system
- Support in audit planning, in the audit itself, and authoring of the resulting audit report

For further information please contact:

Erik Malte Rasmussen
Director, IT Solutions

Lindeq AS Norway

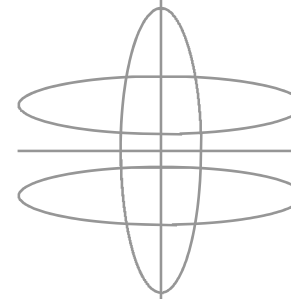
Headquarter
Gjerdrumsvei 12
0484 Oslo, Norway
Phone: +47 22 23 88 80
Fax: +47 22 95 17 27

Lindeq AS Denmark

Erik Malte Rasmussen
Hagelbjergvej 9
4100 Ringsted, Denmark
Mobile: +45 51 90 52 55
Fax: +47 22 95 17 27

Lindeq AS France

27G, rue Maréchal Lefebvre
67100 Strasbourg
France
Phone: +33 3 88 10 58 70
Fax: +33 3 90 20 31 95



Lindeq IT/Systems services

Lindeq has expanded the range of services offered to also include highly experienced assistance in the areas of IT/system based tasks

All Lindeq services are always adapted to fit into your business model and needs: ensuring that you stay in control

MedDRA and WHO Drug Dictionary

Management, Coding, Retrieving, Migration, Upgrades, Training

- Dictionary management ensuring compliance with today's regulatory standards
- Highly controlled coding migrations from e.g. WHO Adverse Reaction Terminology (WHO-ART) to MedDRA
- Migration involves all coded system data or operated on subsets of historic clinical study data or datasets received from license partners
- Identification of any potential need for re-coding as a consequence of the MedDRA up versioning
- MedDRA training: coding, subsequent data retrieval based on the coding
- Preparation of quality SOPs covering coding processes and inherent continuous coding QA/QC process

E2B – implementation and management of ICH E2B ex- and import

- Assistance in choosing your most cost-efficient way of being E2B capable and fully compliant to perform E2B submissions of ICSRs and SUSARs
- Actual E2B implementation and required E2B testing with national regulatory agencies
- Day-to-day practical use and management of E2B

Signal Detection (SD) programmes

- Option to use our cleaned-up FDA AERS data as background/ comparison
- Supply of cost-effective Signal Detection application enabling you to run SD analysis at leisure or have this performed as a Lindeq service.

Management and administration of drug safety and clinical systems

- Design of your documented change control procedures
- Performance of your system management according to your own SOPs and change control procedures.

Management and assistance in system implementation/upgrade projects

- System implementation and upgrade projects
- Project management, providing subject matter expertise, maintaining project documentation and tracking progress of project

Data Migration

- High-quality data migration from old to new systems

Design of queries/reports from drug safety and clinical systems

- Data extractions & data modelling
- Reports with your business critical data. Potentially combined with other types of external data

Compliance tracking applications

- Authoritative reporting compliance tracking applications
- Configuration of compliance reports to be generated automatically and to be distributed in a fully automated fashion

Design of data entry applications

- Data entry applications with entry screens suitably matching the CRF
- Built-in MedDRA and drug dictionary browsing
- Data can be extracted to e.g. SAS datasets for data modelling and analysis

System vendor selection process and projects

- Saving resources and obtaining an expedited project kick-off with clearly defined scoping
 - Assistance in obtaining a contract with fair pricing combined with (only) those system deliverables which are required and have value-adding effect
-