CV addendum – Erik Malte Rasmussen – Historic job details

Present company:	
Year:	Since Nov 2009
Company name:	DataService – My own consultancy company
Position:	Owner and manager
Tasks: (Examples)	Clinical (medical) evaluation of single cases and of potential safety signals. PSUR and CCSI writing. Lecturing/teaching/presenting on MedDRA coding and subsequent data retrieval, including applied use in signal detection systems. Design and development of SAS-based signal detection application working on top of an Oracle-based Argus safety system. Authoring of GxP validation test cases and –scripts for ARISg safety system upgrade. Authoring of GxP validation test cases and –scripts for bespoken reporting compliance tracking system. Design, testing, validation and implementation of E2B-based safety data exchange between two international pharmas. Data mapping between two safety systems for migration to a new system.
Results: (Examples)	Enabling customer to perform the required signal detection efforts. Enabling customer's system vendor to design correct data migration. Providing customer with fully documented and validated setup for electronic exchange of safety data with a license partner.

Previous company and period of employment:	
Year:	May 2007 – Oct 2009
Company name:	H Lundbeck A/S. A Danish headquartered, R&D based pharmaceutical company with some 5,500 employees worldwide
Position:	Head of Section, System Management, Business Support, ISPV
Reporting to:	Head of Department, Business Support, ISPV
Number of staff reporting to me:	4-8
Areas of responsibility:	All IT based systems used in Lundbeck Pharmacovigilance; Includes safety database, E2B gateway, query and report tools, web based CIOMS reporting tool for non-E2B, compliance tool, auto-coders.
Tasks:	Maintain, manage and develop the staff and the above systems. Bridging to other Lundbeck business areas and external parties. Vendor, partner and Agency point-of-contact with regard to systems.
Results:	Greatly improved systems with increased focus on GxP validation. Developed and implemented system for detailed compliance tracking combining data from multiple data sources and DB platforms. Introduced two-way E2B gateway systems working with authorities and partners.

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Previous company and period of employment:	
Year:	May 2005 – May 2007
Company name:	Nycomed. A Danish/Swiss headquartered, (R&D based) pharmaceutical company with some 3,000/11,000 employees worldwide
Position:	Head of Safety and Complaint Systems Management
Reporting to:	Director, Central Pharmacovigilance
Number of staff reporting to me:	2-4
Areas of responsibility:	All IT based systems used in Nycomed Pharmacovigilance; Includes safety database, E2B gateway, query and report tools etc etc.
Tasks:	Maintain, manage and develop the above systems and associated staff. Bridging to other business areas and external parties. Vendor, partner and Agency contact with regard to systems.
Results:	Implementing E2B transmissions and new systems for dictionary management. Leading upgrade as well as implementation projects. Representing pharmacovigilance in integration projects (after acquiring Altana Pharma).

Previous company and period of employment:	
Year:	1999 - 2005
Company name:	Leo Pharma. A Danish headquartered, R&D based pharmaceutical company with some +3,500 employees worldwide
Position:	Senior Information Management Specialist; Information Management Coordinator
Reporting to:	Head of Drug Safety
Number of staff reporting to me:	Varying – up to 3
Areas of responsibility:	All IT based systems used in Leo Drug Safety; Includes safety database, E2B gateway, query and report tools etc etc.
Tasks:	Maintain, manage and develop the above systems and associated staff. Bridging to other business areas and external parties. Vendor and Agency contact with regard to systems.
Results:	Key person in identifying a new commercial safety system. Implemented the first-ever GxP validated system at Leo Pharma: ARISg safety system. Implemented Cognos Impromptu as a controlled, regulatory tool for PSURs and similar regulatory reports. Implemented E2B. Founded Scandinavian ARISg Users Group. Key member, MedDRA EU Industry Group, EMEA JIG member. EMEA E2B Task Force member (elected).

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Previous company and period of employment:	
Year:	1987 - 1999
Company name:	Leo Pharma.
Position:	Principal Clinical Project Coordinator and System Administrator
Reporting to:	Head of Medical Department and Head of Math-Stat Department
Areas of responsibility:	IT based operations. Clinical Studies. Clinical dictionaries. Drug safety and safety systems. Legacy SAS based safety system. Dictionary management.
Tasks:	Setting up the department for PC usage. Clinical studies (project design, protocols, setting up centres, CRFs, clinical analysis, study reports). Drug safety. Creation of a safety database system. Maintain, manage and develop the legacy safety system. Bridging to other business areas and external parties. Implementing MedDRA.
Results:	Implemented (1988) the first-ever business area at Leo which was based on using PCs. Covered all aspects of clinical studies from overall project design, writing individual study protocols, setting up centres, designing CRFs, clinical analysis, writing final study reports. Leader of one of three GCP SOP groups implementing GCP in Leo clinical research. After 1994 increasingly involved in drug safety. Designed and programmed Leo's first safety database system which was in production for five years until 1999/2000. Maintained and developed a 0-cost safety system. Was first Danish company to migrate from WHO-ART and implement MedDRA