TAB C

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Paul E Jansen, PE

Summary of Skills: Strong drug/ biologics device development experience (registration, CMC, manufacturing, quality, business development). Demonstrated success in cross cultural work environments (Japan & EU) and excellent project management skills. Demonstrated ability to think strategically, creatively and tactically ensuring that plans translate into coordinated action. Strong leader, having developed and led through many difficult situations. Excellent relationship skills. Highly respected by peers. Gets results through people (internally and from alliances).

Experience/Accomplishments:

June 2014 – Present Sanofi

- **aVP Medical Devices Development:** Responsible for all medical device and drug device combination product development from ideation through proof of concept as part of the newly created Device Development Unit. Includes management of IP, Competitive Intelligence, Patient Insights, External opportunities, Technology development and Early Stage product development. Lead a team located in Boston and Frankfurt.

July 2006 – May 2014 Sanofi-Aventis

- **Global Head Medical Devices Development:** Major Accomplishments: Successful launch of multiple drug device combination products and BGM systems, design and implementation of devices organization (now 145 people strong in EU and US), several strategic alliances signed, successful completion of patent litigation cases. Creation of a portfolio of 1000+ patent families. Global responsibility for devices development including device research, development and industrialization, business development and post marketing activities. Member of several senior level governance committees. Secretary-General Medical Devices Board.

April 1991 – June 2006 Eli Lilly and Company

- **COO: Project Leader Exenatide (Byetta) Global Brand Team:** Major Accomplishments: Member of the 2005/6 Global Brand Team of the Year and Alliance of the Year. Responsible for leadership of the development programs for alternative delivery of exenatide. This included clinical, toxicology, device, CM&C, manufacturing (including facility construction). The projects are highly leveraged with multiple partners. As a result a significant portion of the responsibility included alignment of strategy and negotiation with the partners. Member of the Global Brand (Byetta) Leadership Team.
- **Global Supply Chain Steward; Parenteral Network;** Major Accomplishments: Successful launch of Alimta, Zyprexa IM and Humatrope Reconstitution Device. Development of and implementation of process improvement plan resulting in improved efficiencies. Creation and implementation of global S&OP process for the parenteral network; freeze dried products. Turnaround of manufacturing relationship at DSM. Most improved alliance in 2003. Responsible for management of global network of parenteral manufacturing nodes, successful launch of new products. Also responsible for third party manufacturing operations related to the parenteral network.
- **COO Prozac Global Product Team;** Major Accomplishments: Divestiture of Sarafem brand in US, 2002 sales 10% over plan, ICH Harmonization of label in EU, approval of multiple indications in US. Responsible for development and implementation of brand strategy for Prozac globally and Affiliate Sales support. Responsible for implementation of all R&D activities related to Prozac. Responsible for business operations of the Prozac franchise which includes Prozac daily, Prozac Weekly and Sarafem (for PMDD) brands.
- **Project Leader Prozac Japan;** Major Accomplishments: Preparation of J-NDA, completion of bridging clinical program. Responsible for successful development of Prozac in Japan. Managed and lead a complex team located in Japan, UK, Canada and USA. Conducted three clinical trials in support

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of J-NDA submission and established strong relationships with key opinion leaders in Japan to support approval. Lead CLCR (Lilly – Chugai joint venture), and all development, medical and regulatory functions for the development program.

- **Manager Marketed Products, Pharmaceutical Delivery Systems (PDS);** Major Accomplishments: Successful introduction of devices for Human Growth Hormone and Insulin devices in Europe, Japan and US, participant in ISO expert group which developed and had published a global pen injector standard. Responsible for Supply and Continuous Improvement of all marketed delivery products. Also responsible for PDS site support services and processes. A highly integrated and leveraged environment. Extensive contact with third party suppliers and manufacturers.
- **Manager, Pharmaceutical Delivery Systems;** Major Accomplishments: Successful development, implementation of strategic device plan, three successful re-certifications of ISO 9001 quality system, Launches of Insulin and Human Growth Hormone Devices. Responsible for all PDS work processes (drug delivery device design, development, manufacturing implementation, quality control and quality assurance.). Lead development teams resulting in successful launch of Owen Mumford, BD Classic 3.0 and Humatropen devices. PDS leverages and integrates medical and device technologies with formulation and container requirements into delivery systems which satisfy the needs of Lilly's global patients and health care professionals
- **Manager, Lilly Analytical and Bioanalytical Laboratories;** Major Accomplishment: Secured mandate and funding to expand lab capabilities. Responsible for both labs operating in Canada - bioanalytical and analytical. Responsible for recruiting and development of all staff, capital purchases, and expense management. Responsible for ensuring all operating and procedural systems for long term operation are in place. Liason with Sunnybrook Hospital to seek out further business development/ collaboration opportunities. Ensure appropriate use of resources to maximize laboratories corporate contribution to accelerating the time to get a product to market. Developed, gained approval for and implemented bioanalytical laboratory including 4 LC – Mass Spectrometers.
- **Manager, Lilly Analytical Research Laboratory;** Major Accomplishments: Built on success of lab, successfully integrated labs into Lilly Research Labs with Corporate Labs. Responsible for recruiting and development of all staff, capital purchases, and expense management. Responsible for ensuring all operating and procedural systems for long term operation are in place. Liaison with Sunnybrook Hospital to seek out further business development/ collaboration opportunities. Ensure appropriate use of resources to maximize laboratories corporate contribution to accelerating the time to get a product to market.
- **Manager, Customer Support Operations, MDD (Medical Device & Diagnostics) Companies;** Major Accomplishment: Successfully creating the MDD entities from multiple companies and optimizing effectiveness and efficiency of the operations. Responsible for all aspects of operation of MDD Companies operating in Canada including Customer Service, Regulatory Affairs (compliance and approval), Technical and Field Service, Systems and support staff. Integrated all Technical/Field Service units under one umbrella group. Implemented after hour service for MDD Companies. Co-ordinated installation of call management system for Customer Service group. Implemented new MDD Company products and systems as they were introduced to Canada.

July 1987 – April 1991 Philips Electronics

- **Manager, Customer Support Centre;** Responsibilities included after sales support activities including training, documentation, hardware and software support, dispatch and call management. Developed and implemented service automation plans. Managed a staff of 27 with accountability for top and bottom line results.
- **Manager Central Support Operations;** Responsible for all service automation development and implementation, dispatch (7 day a week, 24 hours a day), call management and office automation software support. Chairman of Service Quality Committee. Secretary of service management team. Accountable for top and bottom line results. Staff of 17.

July 1986 – July 1987 Husky Injection Molding

- **Global Parts and Service Manager;** Directed $15 million per annum service and parts operation through an international staff of 40. Corporate staff in Head Office, Parts Centre in Buffalo, NY and service technicians throughout North America. Fully accountable for P & L. Operation included logistics, materials management, warranty administration, training, documentation and field service.

April 1983 – July 1986 Philips Electronics

- **Branch Service Manager and Manager Employee Relations;** Responsibilities included all aspects of personnel with the exception of compensation. As Branch Services Manager, responsible for $2.5 million service (sales) revenue in Toronto and Northern Ontario. Supervised staff of 35. Negotiated and sold service agreements, invoiced as required and managed spares inventory. Branch considered a business unit with full P&L accountability.

July 1978 – April 1983 Fiberglas Canada (division Owens Corning)

- **Manager Training and Development, Supervisor Product Development, Product Development Engineer;** Responsibilities included product and process development of GLASCAD exterior sheathing. Promoted to supervisor of several projects. Promoted and transferred to Toronto to implement T&D function. Developed and conducted numerous sales, management and technical training courses across Canada.

Education:

1974 – 1978	University of Toronto B.Sc, Mechanical Engineering
1992 – 1995	University of Toronto MSc Biomedical Engineering (1 course outstanding and not completed due to relocation to US)

Outreach Activities:

ISO TC 84 – Vice Chair & Working Group Convener WG15, Visiting Lecturer Tufts University

Hobbies: Skiing, cycling, hockey, curling, reading, traveling, hiking, swimming, soapstone carving

References: Available upon request