Arthur J. Kawasaki, M.Sc., MBA

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Education

Master of Business Administration (MBA, Marketing) - (2001)
Schulich School of Business, York University, Toronto, ON.

Master of Science (M.Sc., Physiology - Endocrinology) - (1995)
University of Toronto, Toronto Hospital, Toronto General Division, Toronto, ON.

Bachelor of Science (B.Sc., Major: Physiology; Minor: Zoology) - (1990)
University of Toronto, St. George Campus, Toronto, ON.

Professional Experience

Sr. Director, Regulatory & Quality (2015 – present)
Canon BioMedical, Inc.

Sr. Director, Regulatory Affairs & Quality Systems (2014 - 2015)
Canon U.S. Life Sciences, Inc., Rockville MD USA

Organization: Leading the establishment of a US (FDA) QSR and ISO 13485 compliance quality management system (QMS) that includes the building a highly skilled and knowledgeable Regulatory Affairs and Quality organization.
Business: Developed and executed a Quality and Regulatory strategy for an in-house developed innovative IVD assay-instrument system that will lead to US and global regulatory registrations and licensing.

Assistant Adjunct Professor, Medical Device Regulatory Affairs (2014 – present), Rutgers University, School of Health Related Professions, Newark NJ USA

Lecturing: Lectured on Medical Device Regulatory Affairs (RA). Includes the creation and development of lecture and student materials for a Medical Device Regulatory Affairs course in Rutgers' Masters Biopharma program.

World Wide Director, Regulatory Affairs (2011 – 2014), Becton, Dickinson and Company (BD), Diagnostics - Preanalytical Systems (PAS), NJ

Organization: Led the development of the RA team, which included the creation of new effective communication tools, regulatory sensing and reporting mechanisms, establishing RA organizational strategy and vision and the facilitating the harmonization of RA procedures, systems and processes with other BDX business segments and units.
Regulatory: Provided guidance to RA team on the preparation and execution of FDA CDRH and CBER Pre-IDE/Pre-submission/Q-Submission Meetings and the preparation and filing of 510(k) applications (for IVDs and Medical Devices).
Business: Active participation on the BD PAS Leadership Team (LT), WW BDX Regulatory LT and Regulatory Operating Committee.

***(ex-pat assignment)* Director, Regulatory & Quality** (2010 – 2011), Nippon Becton Dickinson Company, Ltd. (BD-Japan), Tokyo, Japan

Organization: Led the development of effective RA, Quality Compliance and Environmental Health & Safety (EHS) functional teams (+39 associates). Including leading and sponsoring "Transformation" activities (e.g. establishing job descriptions, robust career succession plans, functional re-organizations, and mentoring program) for key managers and high potential/performing associates.
Business & Operations:

- Site Implementation Lead for SAP upgrade for BD-Japan.
- Active participation on the BD-Japan, WW BDX Regulatory and Quality LTs.
- Led the Radiation assessment and preventative actions of the BD-Japan Fukushima facility post-March 2011 earthquake,

	tsunami, TEPCO Daiichi Fukushima Nuclear Plant meltdown events.
Advisory Board Member (2006 – 2010), Cliniteca Biosciences International**,** Toronto, ON Canada	Provided clinical, quality and regulatory guidance to the senior management team of CBI, a global clinical research organization (CRO).
Director, Regulatory Affairs and Quality Management (2005 – 2010), Becton Dickinson Canada Inc. (BD-Canada), Mississauga, ON Canada	**Organization & Regulatory:** • Led, managed and coached Quality & Regulatory (Q&R) Team (6 associates) • Q&R liaison with the local and corporate leadership teams for Quality Management and RA and Compliance. • Successfully restructured/re-built the Quality & Regulatory teams to better meet the business needs of the organization. • Mentored two (2) non-Q&R BD-Canada associates **Business:** Active participation on the BD-Canada, WW BDX Regulatory and Quality LTs. **Industry:** Chair, MEDEC Regulatory Affairs Steering Committee for a record 3 consecutive terms.
Lecturer, Introduction to Professional Regulatory Affairs (2003-2006), Academy of Applied Pharmaceutical Sciences (AAPS), Toronto, ON Canada	Created and lectured on course curriculum, lesson plans and materials for introductory course.
Manager, Regulatory Affairs (2002 -2005), BD-Canada, Oakville, ON Canada	**Regulatory:** • Drafted high quality submissions for medical devices, IVDs and drugs. Successfully negotiated 3 priority/expedite reviews for Class III submissions resulting in record approval times (i.e. 24 days vs. Health Canada average of 230 days); and obtained priority review for a Class III submission (i.e. 18 days vs. Health Canada target of 45 days). • Managed the implementation product recalls and adverse event reports to Health Canada. • Supervised and mentored Quality and Regulatory Affairs Associates**.** **Business:** • Participated in a cross functional team which segmented the customers of BD resulting in improved services and resource allocations – cost and time savings • Successfully negotiated with a key pharmaceutical customer a resolution to product shipping issues, saving BD thousands in expenses
Sr. Regulatory Affairs Associate (2002) and R**egulatory Affairs Associate** (2000-2002), Eli Lilly Canada Inc. (Lilly Canada), Toronto, ON Canada	**Regulatory:** • Coordinated regulatory submissions (INDs/CTAs, NDS, S/NDS, NCs and DIN Notifications) for women's health, skeletal and endocrine therapeutic product classes. • Successfully negotiated the appeal process with BGTD to obtain Priority Review status for a NDS **Business:** Participated in cross-functional product teams leading to marketing, clinical and regulatory improvements for products.

Quality Control Associate (1998 - 2000), Lilly Canada, Toronto, ON Canada

- Managed GMP requirements (e.g. batch document review, stability and deviations) for key products. Played an integral role to reduce inventory costs and levels by more than 50%
- Managed and coordinated the Change Control process. Successfully designed a database to track changes impacting Canada and expedite implementation and closure of those changes. Highlight, no observation during a Health Canada GMP Audit (May 2000)
- Managed and coordinated the Stability program. This included revamping the process and bringing the system to GMP compliance. Highlight no observation during a Health Canada GMP Audit (May, 2000)
- Liasing with the affiliates to improve the quality and compliance aspects of importing and distributing drug products.

Quality Control Manager (1995 - 1998), Lorus Therapeutics (formerly: Imutec Pharma Inc.), Toronto, ON Canada

Established and managed a QC and R&D Lab team of 5 associates that drove method development, research and development and performance of QC tests and assays. This included establishing validation protocols and standard operating procedures. Highlight, results were included as part of an accepted IND submission and patent filings.

Professional Development & Awards

- **Regulatory Affairs Certification (RAC**), RAPS (2013 – present)
- **Member, AdvaMed Mdx Task Force**, AdvaMed (2011-2014)
- **Chair, Regulatory Affairs Steering Committee**, MEDEC (2006 – 2009)
- **Leadership Award,** Becton Dickinson Canada Inc. (2004)
- **Leadership** & **Achievement Award**, Eli Lilly Canada (1999, 2000 and 2002)

Academic/Research Awards

- **Juvenile Diabetes Foundation Summer Studentship.** (1994)
- **University of Toronto Open Fellowship.** (1991 - 1992)
- **Medical Research Council Summer Studentship.** (1990)
- **Ontario Scholar Award.** (1986)

Publications

1. **Kawasaki AJ** 2004 *The Tao of Regulatory Affairs*. Pharmaceutical Canada 5(2):30-33.
2. **Kawasaki AJ** 2002 *Negotiations, A Regulatory Perspective*. Pharmaceutical Canada 3(3): 33-34.
3. **Kawasaki AJ** 1995 Investigations of *In Vitro* and *In Vivo* Aspects of Hepatic Very Low Density Lipoprotein Synthesis and Secretion in the Rat. M.Sc. Research Thesis. University of Toronto.
4. Rastogi, KS, Brubaker PL, **Kawasaki, A**, Efendic, S and M Vranic 1993 *Increase in somatostatin to glucagon ratio in islets of alloxan-diabetic dogs: effect of insulin-induced euglycemia.* Canadian Journal of Physiology and Pharmacology 71: 512-517.

Abstracts

5. **Kawasaki, A** and G Steiner 1994 *Comparative Evaluation of Triglyceride Secretion Rates as Determined by Tracer and Triton WR-1339 Methods under MKC-121 Drug (Mistubishi Kasei Corp.), Normal and 10% Fructose Dietary Conditions.* Juvenile Diabetes Summer Studentship Proceedings, University of Toronto.
6. **Kawasaki, A.**, Raman M., James, L. and G. Steiner 1992 *The Effect of Insulin on Hepatic VLDL-TG Secretion and ACAT Activity - Cholesterol Ester Synthesis.* FIPP

proceedings, p. 28, University of Toronto.

7. **Kawasaki, A**, Rastogi, KS, Lickley, L, Efendic, S and M Vranic 1991*Impaired Glucagon Response to Insulin Induced Hypoglycemia in Diabetics: Possibly a Result of an Increased Islet Somatostatin to Glucagon Ratio (SGR).*, FIPP proceedings, p 24., University of Toronto.
8. Rastogi, KS, **Kawasaki, A**, Efendic S, Brubaker, PL and M Vranic 1991 *Increase in Somatostatin to Glucagon Ratio in Alloxan Diabetic Dogs: A Potential Mechanism for Glucagon Irresponsiveness to Hypoglycemia.* Program of the 73rd Annual Meeting of The Endocrine Society, Washington D.C., p. 476.
9. Rastogi, KS, Lickley L, **Kawasaki A**, Efendic S and M Vranic 1990 *Increased Islet Somatostatin/Glucagon Ratio (SGR) in Alloxan Diabetic Dogs: A Putative Mechanism of Glucagon Irresponsiveness to Hypoglycemia.* Program of The Nervous System and Fuel Homeostasis: 1st Toronto-Stockholm Symposium on Perspectives in Diabetes Research, University of Toronto.

Extracurricular Activities

Karate (Black Belt 1st Dan (shodan), Shito-Ryu Itosu Kai Karate**),** tennis, weight training, mountain biking, golf, automotive enthusiast, watercolour painting and sketching**.**

References: Available upon request