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Executive Summary

Dr. LaDuca has spent 30 years in the IVDD business as director, VP and officer, inclusive of entrepreneurial start-ups to multinational organizations. Throughout his career he has provided corporate leadership and management in regulatory, compliance, quality, clinical, medical and product development. This unique combination of expertise has proven valuable in providing strategic oversight to industry as well as practical tactical leadership and operations management. Practical problem solving for all technical and compliance issues is the benchmark of his tenure. His teams have been identified as "Best in Class" by third parties for their expertise and professionalism. As a corporate officer, Dr. LaDuca has successfully managed strategic business transformation with positioning and finalization of the business for sale. He has direct experience in these entrepreneurial settings as well as operations, mergers and Due Diligence projects. At Siemens Diagnostics he was a member of a select team of senior staff responsible for the due diligence and integration of Bayer, DPC and Dade to Siemens Diagnostics. As the CSO member of the Accriva Diagnostics Executive Leadership Team, he was the technical and compliance lead in the sale of the business to IL/Werfen. Following that sale, he established an independent consulting corporation focused on regulatory, compliance and scientific advisory to the medical industry.

Industry Leadership

Dr. LaDuca has served as Chair of the Critical and Point of Care division of the AACC and Chair of the CLSI Point of Care Consensus Committee. He has authored and published numerous technical articles and abstracts and routinely presents at national and international scientific meetings. Dr. LaDuca has been an invited speaker at scientific and FDA meetings, most recently at the FDA's Workshop for Standardization Guidelines for POCT Coagulation Testing and co-chairs the CLSI committee drafting the resulting CLSI Harmonized Standard.

Areas of Technical Expertise

- In Vitro diagnostics tests with globally acknowledged leadership in POCT
- POCT systems for hemostasis, coagulation, platelet function, blood gas, blood electrolytes, blood oximetry, lipoproteins (cholesterol derivatives), glucose, HbA1c, creatinine and urinalysis.
- Laboratory based systems for infectious disease, cardiac markers, general hematology, chemistry, blood banking and molecular diagnostics.
- Invasive medical diagnostic systems including interventional angiography and endoscopy
- Cardiovascular disease management including anticoagulation and anti-platelet regimens
- Hemostasis management for interventional cardiology, cardiac surgery and interventional neurology

Professional Experience

LADUCA RCA, LLC, current
President and Owner
Accriva Diagnostics, San Diego CA, (2012-2017)
Chief Scientific Officer
Polymer Technology Systems (PTS), Indianapolis, IN, (2008-2012)
Chief Science and Technology Officer
Siemens Medical Solutions (SMS) Diagnostics (Dx), Tarrytown NY (2007-2008)
Vice President, Quality and Regulatory Shared Services
Bayer HealthCare Diagnostics Division, Tarrytown NY (2005-2007)
Senior Director Global Regulatory Affairs and Compliance
International Technidyne Corporation (ITC), Edison, New Jersey (1986-2005)
Vice President, Clinical and Regulatory Affairs
Vice President, Quality, Regulatory, Clinical Affairs
Vice President, Research and Development
Director, Medical Research

Business Transformation

Accriva Diagnostic – Under the ownership of the private equity firm Warburg Pincus, this business was founded thru the merger of ITC, a NJ based business and Accumetrics, a California based business. In this successful business transformation, an efficient, compliant production operation was installed with a Gross Margin (GM) increase from 32% to 55%. Sales grew by 16% (YTY), product development was aligned with the product strategic portfolio and a quality system was installed with complete site registration with FDA and global regulatory bodies. In January 2017, the Executive Team successfully sold the business to Instrumentation Laboratories (IL), part of the Werfen Group for $380MM, representing a greater than 4 times ratio to revenue.

PTS – This private held business was on the brink of collapse upon joining in 2008. The business had been issued a FDA Warning Letter and the diagnostic test systems had become imprecise and inaccurate; sales were slumping. The Warning Letter was successfully resolved in 15 months and the core product line rebuilt with new technology. This business was sold in 2016 at 4 times revenue yielding significant return to the shareholders.

Bayer and Siemens Diagnostics (Dx) – Under Siemens, the merger of Bayer, DPC and Dade created a $2.4 Euro diagnostics business. As member of a select due diligence team, Dr. LaDuca assessed and recommended acquisition to Siemens BOD. During merger, he directed all regulatory and legal activities to support the transition on a world-wide basis of the 150 Bayer legal entities to SMS-Dx. This was completed in six months without global business interruption and a single quality management system installed. Served as a member of Product Approval Committee (PAC), which harmonized the product portfolio, approved phase gate product development, cancelling and/or authorizing investment.

Technical Developments, Product Development and Product Registration

Has managed to completion the development of several unique POCT test platforms, yielding eight novel POCT patents. Championed thru the pre-submission & review process the clearance of more than

fifty 510(k)s and approval of eight PMAs, as well as global product registrations, and facility registrations with the FDA and international accreditation bodies, e.g., ISO, CMDR, PMDA, ANVISA, etc.

Regulatory, Compliance and Quality

Organized and executed quality and compliance programs during each professional appointment, including setting up and maintaining quality management systems (QMS), all associated compliance activities, e.g., complaint handling and resolution, CAPA, non conformance, quality training, product development programs and design control, health risk assessments, medical device reporting to FDA and global agencies, Field Corrective Actions and post market surveillance. At PTS, the timely resolution of the company's FDA Warning letter avoided closure of the business and allowed subsequent revenue growth. He has provided audit preparation and inspection readiness guidance for FDA, ISO (CE) and other global agencies.

Medical and Clinical Affairs

At ITC, PTS and Accriva assembled small groups of professionals focused on clinical studies for investigative research, new product evaluations and demonstration of marketed product clinical value. These teams have produced numerous publications and he has authored more than 30 peer reviewed publications, 100 scientific abstracts and 65 invited symposia at scientific meetings, FDA, CDC and ISO workshops.

Education and Training

Hematology Fellow - The Johns Hopkins School of Medicine, Baltimore MD
Ph.D. Experimental Pathology-Hematology – SUNY Buffalo (NY)
M.S. Natural Sciences – SUNY Buffalo (NY)
B.S. Biology – SUNY Albany (NY)

Active Professional Affiliations, Council and Committee Memberships

- Fellow of the American Heart Association (FAHA) Council on Arteriosclerosis, Thrombosis and Vascular Biology
- Member American Association of Clinical Chemistry (AACC)
- AACC Point of Care and Critical Care Division (Chair 2009)
- CLSI Area Committee on Hematology
- CLSI Area Committee for POCT (Vice Chair, 2007-11; Chair 2012-16)
- US Technical Advisory Group for ISO/TC 212
- American Society of Hematology (ASH)
- The Johns Hopkins Medical and Surgical Association
- International Society on Thrombosis and Haemostasis (ISTH)