# Bradford Spring

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| May 2022 to Present | **GLOBAL HEAD OFREGULATORY POLICY & INTELLIGENCE**<br>**Roche Diagnostics, Washington DC**<br><br>♦ Collaborate with key subject matter experts and stakeholders to establish policy positions and advocacy plans, and drive strategic direction for Regulatory Policy and Intelligence, with leadership of a cross-Roche team located throughout the world.<br><br>♦ Build credibility and trusting relationships with regulators and other external stakeholders in collaboration with Roche Diagnostics Quality, Regulatory, Affiliates and other influencers to make Roche a Trusted Partner to regulatory authorities around the world.<br><br>♦ Point of contact on regulatory policy issues with the US FDA, international regulatory agencies and other regulatory bodies, industry organizations and other advocacy groups, supranational organizations, and Regions and Affiliates.<br><br>♦ Develop and drive an integrated, overarching global strategy for shaping the regulatory environment in a manner that advances Roche's interests in the development, manufacturing, marketing and distribution of Roche Diagnostic products.<br><br>♦ Oversee the development and maintenance of a current picture of regulatory policy in individual countries and regions, including an active regulatory intelligence function that gathers, analyzes and communicates timely information and trends regarding regulatory changes, their impact on Roche Diagnostics, and the pathways for influencing policy.<br><br>♦ Partner with external stakeholders, as appropriate, to build alignment with Roche Diagnostics' regulatory policy positions and encourage external advocacy efforts consistent with those positions. (e.g., non-profit associations, industry organizations, think tanks, coalitions).<br><br>♦ Drive knowledge sharing, including training and support for Q&R teams, Customer Areas and others as needed, on key regulatory policy issues, directional changes in regulation, and trends in the regulatory environment. |

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| October 2019 to May 2022 | **VICE PRESIDENT, REGULATORY AFFAIRS – STRATEGIC PLANNING, POLICY & REGULATORY INTELLIGENCE**<br>**Becton Dickinson, Franklin Lakes, NJ**<br><br>♦ Provide strategic regulatory leadership to BD Segments and Regions regarding the sensing, advocacy, interpretation and implementation of global regulations and standards.<br>♦ Contribute to the development and execution of BD's global business strategies to achieve improved time to market and reduced development cost for new medical devices.<br>♦ Provide sound assessments of regulatory pathways and risks, working closely with functional leaders in Marketing, Business Development, Research & Development, Public Affairs, Quality and Medical Affairs.<br>♦ Sense, influence, and act on global regulatory trends that may affect market access for new products or existing products in new markets.<br>♦ Develop and implement global regulatory strategies for innovative products that create competitive advantage.<br>♦ Work with external stakeholders (e.g., AdvaMed) to shape policies affecting BD products and strategies worldwide.<br>♦ Design and implement corporate regulatory affairs organizational designs to achieve business goals, improve efficiency and maintain compliance.<br>♦ Lead a staff of regulatory professionals to assist with strategic planning and policy advocacy activities, developing required competencies, including regulatory knowledge and ability to apply this knowledge, effectiveness in team and one-to-one interactions, and verbal and written communications.<br>♦ Lead the Regulatory Affairs Project Management office to implement new regulations, policies and standards impacting multiple BD business units.<br>♦ Develop and implement a standards management process, create awareness of and influence the content of new standards. Place subject matter experts on standards development committees to shape new requirements. |

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| September 2012<br>to October 2019 | **VICE PRESIDENT, REGULATORY AFFAIRS – DIAGNOSTICS SYSTEMS**<br>**Becton Dickinson, Sparks, MD**<br><br>♦ Accountable for building and maintaining an organization capable of achieving new product portfolio goals through novel regulatory strategies that improve time to market, reduce development costs and create competitive advantage.<br>♦ Lead a team of 30 individuals and five direct reports across four locations in the US and Europe.<br>♦ Create a culture of "constructive challenge" and critical thinking help teams deal with ambiguity, improve predictability and become better business partners.<br>♦ Sense, influence, and act on global regulatory trends that may affect market access for new products or existing products in new markets.<br>♦ Develop and maintain a best-in-class culture of compliance through education, audits and remediation plans.<br>♦ Collaborate with key commercial stakeholders to develop market access strategies that encompass reimbursement, regulatory approvals, government policy, and health economic outcome studies.<br>♦ Navigate a highly matrixed organization by building strong relationships across all functions, resourcing projects and initiatives for on-time delivery, while maintaining a lean budget.<br>♦ Work with government policy teams and external stakeholders (e.g., AdvaMed) to shape policies affecting BD products and strategies.<br>♦ Leading EU MDR and IVDR gap analysis and remediation initiatives to obtain compliance for over 400 technical files by May 2020 (MDR) and May 2022 (IVDR)<br>♦ Implemented two novel regulatory strategies leveraging real-world evidence to achieve product approval for claims two years earlier than the competition and saving over $10M in clinical trial costs.<br>♦ Lead data privacy initiatives for the business to comply with HIPAA, GDPR and other global privacy regulations. Ensure compliance for existing products and processes. Advise product development teams on how to design privacy features into medical devices. |

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| January 2010 to September 2012 | **Director, Regulatory Affairs - Diagnostic Systems**<br>**Becton Dickinson, Sparks, MD**<br><br>♦ Accountable for managing the tactical and strategic regulatory activities for a global IVD business and for maintaining a productive, collaborative relationship between the business and agents of the US FDA and health ministries around the world.<br>♦ Accountable for global registration of products encompassing multiple IVD technologies including, molecular diagnostics, personalized medicine, point of care diagnostics, laboratory automation, antimicrobial susceptibility, specimen collection, and traditional microbiology testing supplies.<br>♦ Experienced in leading the preparation of 510(k), PMA, pre-IDE, EU Notified Body and CLIA Waiver submissions.<br>♦ Promote and protect business interests in interactions with government agencies and other industry personnel (e.g., AdvaMed and product development partners).<br>♦ Assist in the development of new policies, regulations and standards affecting business interests through external trade associations<br>♦ Accountable for assessing and communicating the impact of global developments in regulations concerning the development, marketing and quality of diagnostic products to the business leadership team.<br>♦ Implement ways to continuously drive self and staff to complete business critical work faster and more efficiently than the competition.<br>♦ Direct the activities of twelve geographically diverse regulatory affairs directors, managers, and specialists to achieve global business goals in the most expeditious manner. Responsible for developing employees in their current role and facilitating career development.<br>♦ Work with Business Development and Strategic Marketing to assess the regulatory environment for novel diagnostic technologies and potential acquisition targets. |
| May 2009 to January 2010 | **Market Development Manager for Emerging Markets – Sepsis**<br>**Becton Dickinson, Sparks, MD**<br><br>♦ Nine month assignment tasked with creating market development strategies for new and existing low-cost sepsis diagnostic solutions in developing countries.<br>♦ Leverage key opinion leaders input on diagnostic and treatment best practices.<br>♦ Develop regional educational programs to communicate global best practices in blood culture and promote the value BD brings to sepsis diagnostics. |

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| February 2005 to January 2010 | **PROGRAM MANAGER, BACTEC BLOOD CULTURE SYSTEMS**<br>**Becton Dickinson, Sparks, MD**<br><br>♦ Accountable for delivering three new blood culture products to the market on time, on budget and within scope. Two projects were on parallel paths requiring efficient use of cross-functional resources to meet deadlines.<br>♦ Successfully redirected instrument program in 2005 to reduce instrument costs, improve time to market, and better meet customer needs. Instrument launched on time and under budget.<br>♦ Responsible for leading multifunctional core teams from initiation through product development, transfer to manufacturing and commercialization. Coordinate functions, such as R&D, manufacturing, marketing, finance, clinical affairs, regulatory affairs, and customer service to achieve goals.<br>♦ Facilitate identification of any issues that may delay product or project and take appropriate action. Manage internal and external information flow between team members, senior management and external customers<br>♦ Develop and execute product life cycle management strategies to maintain product viability on the market and grow profitability. |
| July 1999 to February 2005 | **MANAGER, REGULATORY AFFAIRS – DIAGNOSTIC SYSTEMS**<br>**Becton Dickinson, Sparks, MD**<br><br>♦ Accountable for the leadership, coaching and development of regulatory affairs specialists. Provide guidance in the development of performance and career goals.<br>♦ Allocated resources for projects in Identification/Antimicrobial Susceptibility Testing, Rapid Immunodiagnostics, Hematology and Molecular Diagnostics. Developed and implemented worldwide regulatory strategies for in vitro diagnostic products. Managed resources to achieve company goals.<br>♦ Managed and assisted in preparation of over sixty 510(k)s and one Modular PMA submission (subsequently down-classified). Coordinated and conducted pre-IDE meetings with FDA for all products lines.<br>♦ Supported regulatory submissions in EU, Japan, Canada, Asia and Latin America.<br>♦ Worked directly with FDA to define requirements for novel products where regulation and guidance did not exist.<br>♦ Participated on AdvaMed PMA Working Group, IVD Task Force, CLIA Working Group and CLSI Subcommittee on Antimicrobial Susceptibility Testing. |

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| April 1992 to July 1999 | **Regulatory Associate III (Senior Associate)**<br>**Ortho-Clinical Diagnostics, Rochester, NY**<br><br>♦ Developed and implemented regulatory submission strategies for clinical chemistry, immunology, and virology reagents, equipment and software.<br>♦ Prepared Modular PMA submissions for class III in vitro diagnostic reagents. Participated in pre-IDE and agreement meetings with FDA.<br>♦ Prepared 510(k) submissions for new and modified in vitro diagnostic devices.<br>♦ Participated in the development, review, and approval of clinical study protocols.<br>♦ Licensed IVD products in Europe, Japan, Asia and Latin America.<br>♦ Conducted ISO 9001 and GMP audits of various company departments.<br>♦ Planned and conducted risk analyses and FMEAs on IVD reagents, instrumentation and software. |
| 1988 to 1992 | **Laboratory Sales Representative**<br>**Eastman Kodak Company, Shawnee, KS**<br><br>♦ Sold clinical chemistry instrumentation and reagents to hospitals, clinics, reference laboratories, and physician's offices in Kansas and Missouri.<br>♦ Negotiated five year contracts to increase and maintain market share in territory. Doubled market share in territory in 3 years.<br>♦ Successfully demonstrated to customers that while reagent costs were higher, the overall value to the laboratory was superior to our competitors |

## Testimony, Advisory Committees and Conference Presentations (2014 to 2019)

FDA Medical Device Advisory Committee

Microbiology Panel – Industry Representative (non-voting member) 2017 to 2020

Senate HELP Committee Testimony;

Laboratory Testing in the Era of Precision Medicine (September 2017)

China International Medical Device Regulatory (CIMDR) Forum

US Regulatory Reform of In Vitro Diagnostic Tests (August 2019)

The Use of Surrogate Specimens to Validate Diagnostic Tests (August 2017)

The Importance of Diagnostics in Combating Antimicrobial Resistance (August 2016)

Legislative Reform of Diagnostics in the US (August 2015)

Challenges for Laboratories, Manufacturers and Regulators for AST Systems (August 2014)

## Testimony, Advisory Committees and Conference Presentations (cont'd)

Medical Device Innovation Consortium (MDIC)

Chair of the MDIC Diagnostics Steering Committee (2022)

Surrogate Sample Working Group (2016 to 2019)

Real World Evidence Working Group (2017 to Present)

Artificial Intelligence/Machine Learning Working Group (2020 to Present)

Q1 Productions – Clinical Affairs & Regulatory Approvals for Diagnostics

Diagnostic Regulatory Reform: Proposed Alternatives to LDT Guidance (December 2015)

AdvaMed 510(k) Workshop: Instructor (2013-2015)

## Education, Training and Certifications

2017 BD Leadership Difference Program

2010 BD Business Leader Accelerator Program (administered by Korn Ferry)

2007 Leading and Facilitating Team Dynamics (facilitated by Rod Napier, PhD)

2005 BD Advanced Leadership Development Program

2003 Executive Development Program for Senior RA Professionals (Kellogg School)

2001 BD Leadership Development Program for High Potential Leaders

1997 Regulatory Affairs Certification

1988 Bachelor of Science in Biology, Hobart College, Geneva, NY

## Professional Affiliations

Advanced Medical Technology Association (AdvaMed)

IVD Task Force

Antimicrobial Resistance Working Group

FDA Strategy Working Group

International Standards Organization (ISO); TC 210

Association for Medical Diagnostics Manufacturers (AMDM)

Association for the Advancement of Medical Instrumentation (AAMI)

Regulatory Affairs Professional Society (RAPS)