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PROFESSIONAL EXPERIENCE

Roche Diagnostic Solutions
Global Regulatory Affairs
Global Head

As Global Head responsibilities include overseeing 200 regulatory staff focused on in vitro diagnostic (IVD) development in the areas of molecular, sequencing, point of care, tissue, and core lab. Specific responsibilities include:

- Oversight of the development, submission and archiving of all global submissions for Roche Diagnostic products.
- Provide strategic direction to global development teams with leadership team members in Europe and US.
- Point of regulatory contact with the US FDA, EU notified bodies, and international regulatory agencies.
- Monitor the global regulatory environments, and provide assessments of the impact of new and changing regulations.
- Drive the development of best-in-class processes, practices and submissions strategies leading to successful registrations.

Genentech, South San Francisco
Product Development Regulatory
Vice President, Regulatory Data and Content Management, Jan 19-Jul 21

As Vice President responsibilities included overseeing 300 staff in medical writing, strategic labeling, regulatory operations, project management, quality and compliance and data sharing and disclosures. Specific responsibilities include:

- Oversight of the development, submission and archiving of all global submissions for Roche Pharma products.
- Sponsor of the Regulatory Information Management (RIM) program, providing oversight and guidance on scope, budget, organization, and execution of the cross-enterprise program.
- Member of the Product Development Regulatory Leadership Team (PDR-LT).
- Accountable for oversight of investments in non-molecular project in PDR including process, data and technology.

Genentech, South San Francisco
Product Development Regulatory
Global Head Strategic Operations, Jan 18-Present

Capability Development Leader (CDL), Strategic Labeling, Apr 17-Dec 18

As Senior Director responsibilities included the development and execution of the departmental strategy for PDR leading a team of CDLs responsible for assessing the end-to-end processes, governance, organizational design, and technology needed to achieve the desired future state. Responsibilities also include CDL for Strategic Labeling. Specific responsibilities include:

- Led development and review of context analyses, maturity assessments and roadmaps that set the future direction of PDR across all capabilities.
- Led review, prioritization, budget, and execution of non-molecule portfolio.
- Oversight of change management and communication planning and execution for the strategy.
- Alignment and partnership with other non-molecule programs including Faster Filing and Clinical Trial Regulation Implementation (CTRi).
- Sponsor for CTRi, providing oversight and guidance on scope, budget, organization, and execution of the cross-enterprise program.
- Led capability development associated with Personalized Healthcare (PHC) within PDR and in collaboration with the PHC 2.0 Center of Excellence.
- Responsible for reconceiving the content generation of a label. The scope includes Target Product Profile (TPP1) through delivery to the patient.
- Led differentiation phase optimizing the value of the label for patients, physicians and Roche/Genentech at the product and portfolio levels.

Genentech, South San Francisco, CA, Mar 11-Jul 12, Aug 15-Mar 17
Roche, Basel, Switzerland, Aug 12-Jul 15
Product Development Regulatory
Franchise Head, Mar 11-Mar 17

As Senior Director responsibilities included direct global oversight of projects and staff in oncology focused on lung cancer and cancer immunotherapy. Also held interim responsibilities within hematology franchise, including leadership of the Rituxan subcutaneous ODAC team, to gain more experience and knowledge in hematologic malignancies. Specific responsibilities and accomplishments included:

- Led staff of approximately 35 full time employees (FTEs), including approximately five global regulatory leads (GRLs) and two to three line managers. Provided strategic leadership and guidance to GRLs. Ensured line managers provided staff with clear performance expectations and development opportunities.
- Member of the Global Oncology Leadership Team responsible for identifying strategic focus, resource planning, and development planning for staff within the oncology therapeutic area.
- Accountable for content and quality of global submissions within franchise; notable original NDA and MAA submissions within franchise approved in the US, EU and ROW included Tecentriq, Alecensa, Zelboraf, and Erivedge; also

breakthrough designations obtained in the US during franchise leadership included Tecentriq in metastatic urethra bladder cancer (UBC), and Tecentriq and Alecensa in non-small cell lung cancer (NSCLC).

- Development Review Committee (DRC) representative for lung and immunotherapy projects including Tecentriq, Alecensa, and various gRED and pRED projects. Previous DRC responsibilities included Zelboraf, Cotellic, Erivedge, Tarceva and Xeloda.
- Regulatory representative for pRED Oncology Disease Therapeutic Area (oDTA) while based in Basel.
- Active member of the Lung Disease Area Strategy (LDAT) Team.
- Led Cancer Immunotherapy Committee (CITC) Endpoints Taskforce.
- Led successful ODAC for Rituxan subcutaneous held Mar 2017.
- Led staff on projects within Hematology Franchise including anti-CD20 (Gazyva and Rituxan), Venclexta, and polatuzumab vedotin in first half of 2016 (interim role).
- DRC representative for above noted hematology projects and active member of the Hematology Disease Area Strategy (HDAT) Team first half of 2016 (interim role).
- Led influencing activities, including portfolio meetings with EMA, EU National Health Authorities, and FDA OHOP staff, and scientific or policy directed meetings with AACR and LUNGevity. Influencing also included informing key stakeholders of developments in the global regulatory landscape impacting the product portfolio; or reviewing issues, either through written or verbal communication, which could impact future guidance, regulation or policy.
- Management of the department cost center for oncology while based in Basel.

Genentech, South San Francisco, CA
Clinical Regulatory Affairs Department
Regional Site Head, Inflammation; and Team Leader Oncology, Aug 09-Mar 11

As a Director responsibilities included direct oversight of US regulatory aspects of the staff working on inflammation and oncology projects. In parallel, held the role of Global Development Team Leader (GDTL) for Xolair. Staff included regional partners and GRLs. Specific responsibilities included:

- Provided appropriate support and guidance to project leads. Ensured regulatory team was meeting deliverables and timelines. This included oversight of two marketed products, Rituxan and Xolair, and six new molecular entities at various stages in development, pre-IND through Phase II, including vismodegib and polatuzumab vedotin.
- Managed a group with nine employees, including six direct reports.
- Ensured adequate resourcing and succession planning for inflammation and oncology projects based in SSF.
- Managed the department cost center for inflammation projects in SSF.

- Acted as leader within the SSF PDR leadership team helping to ensure development of department goals, communication of management issues, and review of resources and budgets.
- DSTL for Xolair, and responsible for leading all development aspects of the product including ongoing studies for line extensions, post marketing commitments and life cycle management.
- Lead development representative providing strategic guidance at the Life Cycle Team (LCT) and joint project team (Novartis/GNE), and strategic context to the development sub-team (DST).
- Led DST including setting priorities, resolving issues, and keeping senior management informed.

Genentech, South San Francisco, CA
Clinical Regulatory Affairs Department
Senior Manager, Jan 07-July 09

As a Senior Manager responsibilities included direct oversight for US and/or global regulatory aspects of specific early and late stage programs in rheumatoid arthritis (RA), lupus nephritis (LN), relapsing remitting multiple sclerosis (RRMS), and primary progressive multiple sclerosis (PPMS). Specific responsibilities included:

- Acted as regulatory lead on the core team and joint project team (Roche/Genentech) for ocrelizumab, in late stage development for indications in RA, LN, RRMS and PPMS.
- Led the filing and clearance of Investigational New Drug Applications (INDs) for SLE/ LN, RRMS and PPMS.
- Provided strategic guidance for ocrelizumab for ongoing development programs, additional development options assessed through life cycle management, and competitor threat assessments.
- Managed project leads for each indication for which ocrelizumab was being developed and provided strategic guidance for three early stage programs in RA; group included six employees, four being direct reports.

VaxGen, Inc. Brisbane, CA
Regulatory Affairs Department
Manager-Director, July 00-Dec 06

Responsibilities included primary oversight for regulatory aspects of vaccine programs. As Manager and Senior Manager responsibilities included oversight of pre-licensing and compliance activities required to support the development of the first preventative HIV vaccine, bivalent recombinant glycoprotein 120 (rgp120), to enter and complete Phase III clinical studies. Responsibilities also included primary oversight for regulatory aspects of the recombinant protective antigen (rPA) program, a vaccine for anthrax.

Baxter Healthcare Corporation, Hyland Immuno, Glendale, CA
Regulatory Affairs Department
Specialist-Senior Specialist, Sept 97-Feb 00

Responsibilities as a Specialist included providing regulatory oversight of immune therapy and critical care products derived from human plasma, including immune globulin intravenous (IGIV) and albumin.

The Weinberg Group Inc., Washington, DC
Pharmaceutical and Medical Device Practice
Research Associate, Apr 96-Jul 97

Assisted consultants in providing developmental, regulatory, and litigation support to pharmaceutical, medical device, and food industries.

EDUCATION
University of California, Santa Barbara, Mar 95
B.A., Biology
B.A., Environmental Studies