Frank Dieterle, Ph.D.

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Professional Experience

A dynamic thought leader who has built and led global teams and units successfully developing and commercializing world-class diagnostic tests, companion diagnostic tests and medicines. Passionate about bringing innovative and transformative healthcare solutions to patients and physicians by translating insights into value propositions, formulating strategies, and driving innovation, development and operational execution through a positive inspiring culture and cross-functional leadership.

- 15 years of experience in the pharmaceutical industry with positions of increasing responsibility in IVD, drug development and companion diagnostics development.
- Global leadership experience in the roles of Site Head of Novartis Kent (UK, 80+ associates), Head of the Novartis Near Patient Testing Unit (NPT, 90+ associates), Global Program Leader for Novartis Companion Diagnostics programs and Consortium Director of the international multi-company consortium IMI SAFE-T.
- Successfully developed the business case to acquire the point of care biotech startup VIVACTA (90m USD) and executed the integration into Novartis and built-up of an ISO-13845-certified Novartis site for development, manufacturing and commercialization of IVD test with a development pipeline of multiple IVD tests in the areas of Allergy, Asthma, Cardiovascular and Infectious Diseases to complement Novartis drugs through simplified diagnostics.
- Successfully developed and commercialized the first-ever IVD point of care platform of Novartis Pharma (Niji™ point of care system) and the first IVD test on the platform (Total IgE) launched in multiple countries.
- Development of all aspects of the Niji™ platform from early prototypes to commercial tests under design control: Hardware (Niji™ reader), software / firmware (reader and servicing tools) and reagents / cartridges for the entire IVD test portfolio.
- Multiple years of experience in drug development and companion diagnostics launching several drugs and associated tests in Nephrology and Transplantation (e.g. Certican™).
- Multiple years of experience in technology innovation and in advanced data analytics successfully developing and launching customer-focused solutions improving patient outcomes and impacting business results within different areas of Pharma but also in private – public collaborations.
- Successfully led the NPT business unit and 90 employees through a reorganization and subsequent transfer and closure of the unit and site.
- Author of more than 40 publications in high-impact journals (e.g. Nature Biotech.)

Professional Activities

2005-2018: Positions within Novartis (Switzerland and UK)

Global Head Near Patient Testing Unit (CEO, 2018)

- Responsible for all aspects of the Near Patient Testing unit (integrated unit for the development, manufacturing and commercialization of point of care in-vitro diagnostic tests with 90+ associates).
- Successfully led the change management of NPT after the strategic decision to exit point of care IVD business including transfer, out-licensing and decommissioning of the entire IVD unit and Novartis Kent Site.

Global Head Development and Manufacturing, Near Patient Testing Unit; Site Head Novartis Kent Site, UK (2016-2018)

- Responsible for the Diagnostic Development function and GMP manufacturing of multiple IVD programs from research to post-launch support (60+ associates).
- Site Head of the Novartis Kent Site, UK (80+ employees) with full accountability of all aspects of the ISO 13485-certified site and associated operations for IVD development, manufacturing and commercialization.
- Established and executed a pipeline of IVD development projects in the area of allergy, asthma, infectious diseases and transplantation and launched the Niji™ total IgE point of care test in several countries.

Head New Products & Medical, Near Patient Testing Unit (2012-2016)

- Accountable for the portfolio of research and development programs and strategic plans leading to the growth of a new diagnostics unit from initial incorporation to a stand-alone business unit developing multiple IVD programs with 90+ associates (~20m USD yearly budget).
- Responsible for the diagnostic strategy, value propositions, commercial business cases and diagnostic upsides of global complementary and companion IVD programs in various therapeutic areas across the entire Novartis Group and for obtaining support and funding from Novartis top leadership resulting in an IVD pipeline of 10+ projects.
- Key responsibilities for the business case and acquisition of the biotech company Vivacta (90m USD), integration into Novartis, growth and transformation into an ISO 13485-certified Novartis site for development, manufacturing and commercialization of IVD tests.

- Acting Deputy Head of the Near Patient Testing Unit with co-responsibility for the R&D function.
- Led multiple due diligences for personalized medicine projects and acquisitions of biotech companies and IVDs across entire Novartis (e.g. publicly known Google-Alcon "Smart Lens" deal for real-time monitoring of glucose) and established multiple external diagnostic collaborations (e.g. collaboration with the Bill and Melinda Gates Foundation).

Global Program Director, Companion Diagnostics (2011-2012) and Molecular Diagnostics (2009-2011)

- Global Program Diagnostics Director for in-vitro diagnostic (IVD) and companion diagnostic programs with full strategic, financial and cross-functional team responsibility ranging from business case and proof of concept to diagnostic development, clinical trials and market access.
- Consultation of global teams across the Novartis Group on Personalized Medicine strategies leading to initiation and launch of several companion diagnostic tests and IVD tests in house and through partnerships (e.g. Everolimus TDM).

Global Project Team Member, Translational Medicine (2007 - 2012)

- Global project team representative for Translational Medicine in two global drug development programs in transplantation and nephrology ranging from phase II to IV with successful launches of Certican™ in multiple indications and launch of the IVD TDM assays through partners.
- Responsible for all aspects of Translational Medicine for assigned programs.

Director of the International IMI SAFE-T Consortium (2009 - 2010)

- Consortium director of the SAFE-T consortium of the European Innovative Medicine Initiative (IMI) consisting of 11 pharma companies, 10 academic institutions and 4 biotechnology companies which obtained FDA and EMA qualification of several translational safety biomarkers.
- Co-founder of the SAFE-T consortium; successfully raised € 36m research budget from industry and the European Commission.

Head Safety Biomarkers and External Affairs iTox (2007 - 2009)

- Co-leader of the C-Path Institute's Predictive Safety Testing Consortium (PSTC) nephrotoxicity group, a multi-company consortium to combine data and analyses of biomarker and toxicology studies to obtain regulatory endorsement for using these markers in clinical studies.

Project Leader Safety Biomarkers (2005 - 2007)

- Co-leader of the first-ever submission of biomarkers and approval as drug development tools by FDA, EMEA and PMDA later published in several Nature Biotechnology articles and multiple press releases.
- Project leader of a Cooperative Research and Development Agreement between Novartis and FDA for establishing and applying new guidelines for biomarker qualification; later implemented into law as "Qualification of Drug Development Tools" under new FD&C Act Section 507.

2003 – 2005: F. Hoffmann-La Roche, Basel, Switzerland

Research Scientist in Pharma Research, Enabling Sciences

- Implementation of big data analytics of metabonomics and cross-functional "-omics" data to identify biomarkers and to obtain molecular insights into drug toxicity to support pre-clinical and clinical drug safety.

2000 – 2003: University of Tübingen, Germany

Research Assistant in the Research Group Prof. Dr. G. Gauglitz, Analytical Chemistry and Informatics

- Team leader of a group of Ph.D. students in the area of (bio-)sensors, digital technologies and bioinformatics with the focus on deep learning, artificial intelligence and multivariate data analyses.

Education

2003	Ph.D. (summa cum laude): "Multianalyte Quantifications by Means of Integration of Artificial Neural Networks, Genetic Algorithms and Chemometrics for Time-Resolved Analytical Data", University of Tübingen, Germany. Awarded best Ph.D. thesis of 2003.
2000	M.Sc. Chemistry, (Diplom Chemiker, 1.0): "Multivariate Datenanalyse", University of Tübingen, Germany.
1995	B.Sc. Chemistry (Diplomvorprüfungen, 1.0), University of Tübingen, Germany.
1993	High school graduation (Abitur, 1.0), at the Geschwister-Scholl-Schule in Tübingen, best graduate in South-Western Germany.

Personal Information

Languages	German (native), English (fluent), French (basic)

More information and references available upon request.