Gian Nicola Berti

PhD Chemistry

Profile

An accountable and consistently performing senior executive with +20 years of international broad and in-depth experience within a multinational pharmaceutical environment, having covered technical and managerial roles in areas such as quality, development, manufacturing, and general management. Solid track record of successfully leading multifunctional teams, naturally bridging the gap between functions. Consistently driving performance, under stretched deadlines while never compromising on ethical, quality and safety standards. Well skilled and structured in problem solving, interpersonal skills, and working under pressure. Empathic and inspiring, empowering direct and indirect reports and cross-functional teams. Passionate about LEAN (LEAN Six Sigma Green Belt) and managing through change. Certified as Qualified Person according to the Italian legislation, with proven track record in health authority inspections. Engaged as board member of the chemistry association of the region of Trentino/AltoAdige and as member of the general council of the industrial association of theTrentino province.

Core competences

General Management and Change Management, API Manufacturing, Sterile Manufacturing, FDA Inspection Handling, GMP& Compliance, LEAN-Six-Sigma, Coaching & Empowerment, Technical Transfers, Validation, Start-up of new processes and facilities, presentations and public speaking, management of cross functional teams, business acumen, problem solving, conflict management, managerial courage, hiring and staffing, action oriented perseverant and driving for results, approachable and compassion acts in fairness to direct reports, optimistic and visionary puts ethics, trust and integrity as basis for his actions.

Major Achievements

In General Management: start-up of sterile API manufacturing plant in India, Introduction of LEAN Thinking as core site philosophy and improving productivity of production line by 40%, acting as change agent for several LEAN projects in manufacturing, maintenance and quality, acting as change agent for the Group Quality Culture Change program at Business Unit level. Incrementing the production output of the site within 5 years by 300% while keeping constant the headcount. Reorganization of the site leadership and operational structure as follow in line with Novartis Tech Ops requirements.

In Manufacturing: successful transfers and introduction of several new production processes to the site, but also closure and restructuring of production lines and restructuring of site with reduction of workforce by 40%.

In Quality: Introducing GMP system into quality Lab, construction and design of new QC lab facility, Tech transfer of API Manufacture, including all aspects from QC, manufacturing validation up to FDA approval, conduction of several FDA inspections and national health authority inspections from 2000 to 2019 in different roles, as front man, leading the back office and subject matter expert.

Development: development of different production processes for API's, like methylene chloride free process for API, start-up of new downstream line, several tech transfer of API production process from site to site.

Work history overview

1994 – 1996 University of **Innsbruck** (Austria)

1996 – 2002 Biochemie SpA **Rovereto** (Italy)

2002 – 2004 Sandoz GmbH **Kundl** (Austria)

2004 - 2007 Sandoz Industrial Products SpA, **Rovereto** (Italy)

2008 -2008 Sandoz Private Limited, Turbhe, **Mumbai** (India)

2009 - now Novartis Technical Operations - **Rovereto** (Italy)

Language and IT knowledge

german and italian native speaker, english full professional proficiency, french and spanish basic and school knowledge, Windows, Word, Excel, PowerPoint, Outlook, SAP, Internet, APP's, iPhone, Mac.

Professional experiences

Novartis Technical Operations Rovereto - Sandoz Industrial Products SpA
(Subsidiary of Sandoz GmbH Kundl, Novartis Group, belonging to Novartis Technical Operations Organization as part of the Anti-Infectives platform, specialized in the production of active pharmaceutical ingredients and intermediates via fermentation, downstream and chemical synthesis processes)

since Jan 2009 **Site Head (Plant Manager) and Managing Director** and member of the Novartis Italy Country Executive Committee, reporting to the Global Head of ChemOps and AntiInfectives Platform within the Novartis Technical Operations Organization.

Field of responsibility: responsible management of the whole site including legal responsibility and responsibilities on budget figures achievement, management of statutory obligations of the site in terms of safety, environment, employment. Management and achievement of site objectives and Key Performance Indicators, Responsibility on operational expense and capital expense budget. Management motivation and development of site personnel. 11 direct reports, 150 people HC on site + 80 contractors, Overall size of operations 80-85 Mio EUR sales/year.

Main focus on: ensuring continuous improvement and cost optimization while maintaining compliance to national law and group policies, ensuring high quality and safety standards at the site. Assuring the implementation and compliance of group guidelines and directive, guaranteeing the output in terms of quality and quantities agreed on budget level. Management of the site cost and production budget, keeping relationship to local authorities and local community, interacting at company level with the global divisional and group community. Coaching and development of talents and co-workers.

Major Achievements: Incrementing the productivity of the site by 300% within 5 years with constant HC, Introducting LEAN Thinking as site philosophy, Piloting, introducing and spreading of a Group Quality Culture Change program, the site has been awarded with family audit and best place to work certifications. Preparation and succesful management of 3 FDA Inspection (2011, 2015, 2017), and 5 national Health Authority Inspections, integrating the site into the new Novartis Manufacturing Organization and changing the cultural approach from Sandoz Division oriented to Novartis Corporate oriented. Winning of Italy Top Employer Reward for 2016, 2017 and 2018.

Sandoz Private Limtd. Turbhe / Navi Mumbai / India
(Part of Sandoz AI Group, Novartis Group, production of oral and sterile active pharmaceutical ingredients and sterile finished dosages)

Mar 2008 – Aug 2008 **Site Head (Plant Manager),** reporting to the Head of the Business Unit Anti-Infectives of Sandoz

Field of responsibility: responsible management of the whole site with responsibilities on budget, spending, investments and personnel. 150 people HC on site + 150 contractors, 20 Mio USD sales

Main focus on: start up and validation of sterile API production facility
selection and recruitment of a local successor.
management of post investment phase with downsizing of workforce.

Major Achievements: adequate successor for the role in place from Aug 2008 on, Sterile media fill runs performed successfully, downsizing from 300 FTE to 150 the external workforce of the site.

Sandoz Industrial Products SpA Rovereto / Italy
(Subsidiary of Sandoz GmbH Kundl, Novartis Group, production of active pharmaceutical ingredients and intermediates via fermentation, downstream and synthesis)

Jan 2004 – Mar 2008 **Production Director**, reporting to the Site Head
(+ Sept 2008 – Dec 2008)

Field of responsibility: responsible management of the Biotechnical Production Department in terms of GMP, Health safety and environmental and legal policies. Departments: Fermentation, Downstream, Synthesis, Solvent Recovery, 5 direct reports, 150 people in staff (after restructuring 90 people in staff)

Main focus on: establishing year to year budgets in accordance with marketing and supply chain management, and coordinating with operational departments of engineering and quality
production planning, control and reporting, respecting budget values in terms of personnel, investments, and production costs.
career development management and mentoring of talent personnel
implementation of cost reduction and production maximizing measures

Major Achievements: successful passing of 2 FDA Inspection, May 2004, and Sept 2007 (all with zero form 483 observations)
introduction of new products in existing production facilities, (statins, mycofenolic acid), planning and execution of a huge site reorganization and restructuring program including a 40 % reduction of staff. managing continuous growth an new product introduction at the site Rovereto

Sandoz GmbH Kundl / Austria
(Novartis Group, production of active pharmaceutical ingredients and intermediates via fermentation, downstream and synthesis, sterile and oral solid and liquid finished dosage forms, site with >3000 People, 1 bln€ Sales)

Sept 2002 – Jan 2004 **Production Area Manager**,
responsible for the Sterile Cephalosporin Production Plant, reporting to the Process Unit Head for Sterile Productions

Field of responsibility: Sterile Cephalosporin production plant, responsible management of direct reporting staff ca. 20 people staff, in accordance with GMP and HSE standards, guaranteeing quality and safety standards, respecting production schedule and validation activities.

Main focus on: production planning/execution and control according to budget values evaluation and measurement of plant efficiency according to key performance indicators, implementation of cost reduction and throughput increasing measures, Validation and Registration activities

Major Achievements: successful passing of FDA inspection with no observation for the sterile plant, 20 % increase in production capacity via optimization of cleaning and validation periods and proper campaign programming. Startup of new sterile manufacturing process for the plant (Ceftiofur).

Biochemie SpA Rovereto / Italy (Now Sandoz Industrial Products SpA)
(subsidiary of Biochemie GmbH Kundl, Novartis Group, production of active pharmaceutical ingredients and intermediates via fermentation, downstream and synthesis)

2000 – 2002 Production Area Manager responsible for Chemical production and solvent recovery, reporting to the Head of Production, 5 direct reports, ca. 80 people staff.

Field of responsibility: responsible for Tiamulin, 7-ACA, Erythromycin and Solvent Recovery Production Departments, as well as process development Laboratory, management of direct reporting staff, 5 direct reports, ca. 80 people staff.

Main focus on: production/investment planning and control according to budget, measures for capacity increase in Tiamulin production, shutdown of 7-ACA production plant, Upscaling of new production process for a new Pleuromutilin Derivative, Project for capacity enlargement of solvent recovery for clavulanic production,

Major Achievements: passing of 1 FDA pre-approval inspection for an API production plant with zero 483, successful transfer and validation of new chemical synthesis process of Pleuromutilin Derivative.

1998 – 2000 **Head of Process Development Laboratory**, reporting to the Head of Quality Assurance, management of 2 direct reports

Field of responsibility: responsible for the continuous development of existing production processes, for downstream and chemical synthesis, as well as troubleshooting assistance for production, and the general GMP coordination of the site

Main focus on: Transfer and upscaling of Chemical synthesis processes, Development of Downstream process, Transfer of Production methodology from development in Kundl (Austria) to Production in Rovereto, start up support of new downstream processing, introduction of SAP quality module for product release, validation coordination for the site

Major Achievements: Development of an API Downstream process without use of chlorinated solvents, awarded with the Novartis Leading Scientist award, successfully performed 3 validation batches including validation documentation.

1996 – 1998 **Head of Quality Control Laboratory**, reporting to the Head of Quality Assurance, direct management of 10 people in staff of the Quality Control Laboratory

Field of responsibility: responsible for the quality control and release of raw materials, Intermediates and Finished API &GMP coordination of the group

Main focus on: implementation of a new GMP-compliant quality System according to the new gropu standards, revamping and upgrading of the quality control laboratory, preparation and validation of analytical methods, transfer of analytical methods and specifications for new products, personnel training, preparation of DMF documentation for Europe, and USA

Major Achievements: new laboratory designed and constructed (800m3 of lab space), > 300 analytical methods, > 100 SOP's written, transfer of production and analytical methods from a site in France to Rovereto.

University education and experience

1994 – 1996 Employment at the Leopold Franzens University of Innsbruck as **technical assistant**, holding lectures and organizing laboratory practices.

1993 – 1996 **PhD** study at the thesis at Leopold Franzens University of Innsbruck at the institute for analytical chemistry and radiochemistry, completion of the studies with a PhD thesis in analytical chemistry with the title: “Investigations in ion-pair reversed phase chromatography of DNA”

1988 – 1993 **Bachelor** in chemistry at the Leopold Franzens University of Innsbruck, completion of the studies with a master thesis at the institute for analytical chemistry and radiochemistry with the title: “chromatographic analysis of fluorescence dye labeled oligonucleotides and DNA-fragments”

Publications:

C. G. Huber, G. N. Berti, G. K. Bonn, P. J. Oefner, T. Haemmerle, F. G. Falkner, Application of Alkylated Poly-Styrene/Divinylbenzene Stationaly Phases in Biomedical research, Posterpresentation at HPLC 95, June 1995, Innsbruck (A)

P. J. Oefner, C. G. Huber, F. Umlauft, G. N. Berti, E. Stimpfl, G. K. Bonn, High-Resolution Liquid Chromatography of Fluorescent Dye Labeled Nucleic Acids, Analytical Biochemistry, 223 (1994) 39-46.

C. G. Huber, G. N. Berti, Detection of Partial Denaturation in AT-Rich DNA-Fragments by Ion-Pair Reversed-Phase Chromatography, Anal. Chem, 1996, 68, 2959-2965.

Major professional education and training

- **Behaviour Based Safety**, "The DuPont method" (1999)
- Coaching for High Performance Ashridge Consulting
- **Harvard Business School**, Business Finance I – Sept. 2002, Harvard Business School, Boston, MA
- Novartis, "Leading at the Frontline" – Mar/June 2003
- Novartis, "The role of the leader", June 2006
- **Harvard Business School**, Business Finance II – June. 2007, Harvard Business School, Boston, MA
- **Tuck School of Business**, "Advanced Leadership" Hanover, NH, - Apr 2010
- Novartis **Quality Masters** Program, 4 wks. training, on quality and regulatory in Drug Development, API manufacturing Finished Product manufacturing (2013-2014)
- **LEAN Six Sigma Green Belt** training program and certification (2015)

Sports and hobbies practiced during free time

Sport activities like skiing in winter, in summer trekking and biking in summer, to keep healthy I practice regular walking and swimming in the morning before coming to work, and practicing golf. Together with my wife we like to travel visiting new places in Italy as well as abroad. In the past during school and university studies I studied classic piano at the conservatorium of Innsbruck, which now from time to time I refresh.

Rovereto, May 2019

Gian Nicola Berti
FIRMATO IN ORIGINALE