Fredrik Nicklasson

Curriculum Vitae

PERSONAL DATA

Name:	Fredrik Nicklasson
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PROFESSIONAL EXPERIENCE

In November 2013 I started up Scius Pharma Support AB, an independent consulting firm aimed to support product development initiatives of life science companies of all sizes.

Before that, I have worked as line manager, project manager and specialist in the CMC area of the pharma industry for over 13 years. My main expertise lies within the area of formulation development and dosage form design, stretching from proof of concept work through to tech transfer for commercial production of drug products.

I have set up and executed several projects with contractors in the fields of material characterisation, product development and manufacturing of drug products. This work has involved establishing contracts and agreements as well as monitoring work progress and compliance with quality standards, such as cGMP.

Working cross-functionally within an international pharmaceutical company has given me experience in broad science-based decision making, as well as experience in working with international teams together with professionals from Europe, Asia and the Americas, both inside the company as well as with third parties.

Other types of assignments I have some experience from includes technical due diligence of potential acquisition targets and IP protection work. I am co-inventor of several patents and have also served as technical expert in patent litigation cases.

My experience from working in the fast-paced OTC segment has allowed me to be part of several successful product launches. It also has provided me with ample opportunity to work closely with the marketing organisation within the companies, thus gaining valuable insights in the business aspects of drug development.

My professional background, together with my scientific background as a pharmacist with a PhD in pharmaceutics, gives me a broad understanding of drug development and commercialisation.

EMPLOYMENT HISTORY

McNeil AB (A Johnson & Johnson subsidiary)
2006 - 2013

Pfizer Inc.
2003 - 2006

Pharmacia Corporation
2000 - 2003

Roles and responsibilities:

Manager Formulation Development (2009 – 2013)
Team manager (line manager) leading a product development team of 6-8 colleagues working with formulation development and GMP-manufacturing for clinical studies in phase I and phase III as well as 1/10 scale regulatory stability batches. The team included both junior and senior personnel. The role included responsibility for:

- Regulatory quality of the deliverables of the team.
- Planning and follow-up of the tasks of the team.
- Resource allocation to secure the project deliveries.
- Performance planning and review (goals and objectives, annual salary and bonus review).
- Coaching of individuals and teams to increase team effectiveness.
- Scientific and professional development of individuals in team.
- GMP compliance of the team.
- Occupational safety, health and environment compliance of the team.

New Product Development Project CMC Coordinator (2006 – 2013)
Coordinator of R&D activities in support of NPD (New Product Development) projects. Lead cross-functional R&D teams (CMC Regulatory, clinical, formulation and analytical development). The role included responsibility for:

- Planning overall R&D activities for the project, including cost and resource requirements.
- Execution of R&D deliverables according to project timeline.
- Operational decision-making on pivotal and supporting studies.
- Reporting progress to project governance and stakeholders.

Specialist Formulation Development (2000 – 2009)
Formulation specialist with progressively more senior responsibilities (organisational titles: Research Scientist, Senior Research Scientist, Research Associate, Senior Research Associate). The role included a wide variety of work assignments, from hands-on to purely intellectual, giving experience in areas such as:

- Planning and executing batch manufacture in laboratory scale and up to 1/10 scale.
- Developing formulations from prototype to tech transfer (solid, semisolid and liquid dosage forms).
- Performing activities under GMP (manufacturing, training, qualification, validation, documentation).
- Developing CMC documentation for regulatory files.
- Scientific evaluations of external technologies.
- IP and patents (patent writing, freedom to operate evaluations, competitor activities monitoring, patent defence).

EDUCATION

PhD Pharmaceutics, 2000
Uppsala University, Sweden

MSc Pharmacy, 1994
Uppsala University, Sweden

MEMBERSHIPS AND FELLOWSHIPS

Swedish Academy of Pharmaceutical Sciences (including role as secretary of the Section for Pharmaceutics & Biopharmaceutics 2007-2009)

ADDITIONAL INFORMATION

Languages:

- Swedish, native language
- English, fluent
- German, basic

PUBLICATIONS

2004	Multivariate methods in the development of a new tablet formulation: Optimization and validation., Drug Dev. Ind. Pharm. 30, 1037-1049.. Authors: Gabrielsson, Lindberg, Pålsson, Nicklasson, Sjöström, Lundstedt.
2003	Multivariate methods in the development of a new tablet formulation., Drug Dev. Ind. Pharm. 29, 1053-1075. Authors: Gabrielsson, Lindberg, Pålsson, Nicklasson, Sjöström, Lundstedt.
2001	Compression shear strength and tableting behavior of microcrystalline cellulose agglomerates modulated by a solution binder (polyethylene glycol). Pharm Res 18, 873-877. Authors: Nicklasson, Alderborn.
2000	Compression mechanics of pharmaceutical aggregates – studies on the tabletting of spheronised aggregates with varying composition and porosity, Ph. D. Thesis, Uppsala university. Authors: Nicklasson.
2000	Analysis of the compression mechanics of pharmaceutical agglomerates of different porosity and composition using the Adams and Kawakita equations. Pharm. Res. 17, 949-954. Authors: Nicklasson, Alderborn.
1999	Modulation of the tabletting behaviour of microcrystalline cellulose pellets by the incorporation of polyethylene glycol. , Eur. J. Pharm. Sci. 9, 57-65. Authors: Nicklasson, Alderborn.
1999	Tabletting behaviour of pellets of a series of porosities – a comparison between pellets of two different compositions. , Eur. J. Pharm. Sci. 8, 11-17. Authors: Nicklasson, Johansson, Alderborn.
1999	Occurrence of fragmentation during compression of pellets prepared from a 4 to 1 mixture of dicalcium phosphate and microcrystalline cellulose. Eur. J. Pharm. Sci. 7, 221-229.. Authors: Nicklasson, Johansson, Alderborn.
1998	Effect of pellet size on degree of deformaion and densification during compression and on compactability of microcrystalline cellulose pellets, Int. J. Pharm. 163, 35-48. Authors: Johansson, Nicklasson, Alderborn.

PATENTS

WO2011038104 A2
Process For The Manufacture Of Nicotine-Comprising Chewing Gum And Nicotine-Comprising Chewing Gum Manufactured According To Said Process
McNeil PPC Inc
Inventor(S): Hugerth, Lindell, Nicklasson, Hendenstrom, Koll, Sowden, Luber, Kriksunov, Bunick, Chen, Olsson, Szymczak.
Application No. WO2010US49974A, Filed:20100923 , Published: 20110331

WO2010044736 A1
Multi Portion Intra-Oral Dosage Form And Use Thereof
McNeil AB
Inventor(S): Lindell,; Thyresson, Nicklasson, Bunick, Luber, Hugerth.
Application No. WO2009SE51163A, Filed:20091013 , Published: 20100422

WO2008140373 A1
A Liquid Formulation For Administering Nicotine
Mcneil AB
Inventor(S): Hedenström, Nicklasson.
Application No. WO2008SE279A, Filed:20080421 , Published: 20081120

WO2008140372 A1
Coated Oral Nicotine Formulation Buffered With Amino Acid
McNeil AB
Inventor(S): Andersson, Bergengren, Bosson, Hugerth, Nicklasson, Olsson.
Application No. WO2008SE278A, Filed:20080421 , Published: 20081120

WO2008140371 A1
Oral Nicotine Formulation Buffered With Amino Acid
McNeil AB
Inventor(S): Andersson, Bergengren, Bosson, Hugerth, Nicklasson, Olsson.
Application No. WO2008SE277A, Filed:20080421 , Published: 20081120

WO2007133140 A1
Pharmaceutical Product For Intraoral Delivery Of Nicotine Comprising Trometamol As Buffering Agent
McNeil AB
Inventor(S): Steen, Dymitrowics, Hugerth, Waltermo, Pålsson, Olsson, Nicklasson, Schlüter, Thyresson, Mody, Bosson, Lindell.
Application No. WO2007SE364A, Filed:20070418 , Published: 20071122

WO2005089728 A3
Means For Transdermal Administration Of Nicotine
Pfizer Health AB
Inventor(S): Lindell, Nicklasson, Thyresson.
Application No. WO2005IB673A, Filed:20050310 , Published: 20060511

WO2004084865 A1
Formulations Comprising An Active Ingredient And Cocoa Powder And Use Thereof
Pharmacia AB
Inventor(S): Lindberg, Lindell, Martino, Nicklasson, Thyresson.
Application No. WO2004IB860A, Filed:20040316 , Published: 20041007

WO2004084864 A1
Formulations Comprising Tolterodine And Cocoa Powder And Use Thereof
Pharmacia AB
Inventor(S): Lindberg, Lindell, Katarina, Martino, Nicklasson, Thyresson.
Application No. WO2004IB859A, Filed:20040316 , Published: 20041007