Senia Johansson

PH.D. (PHARM), VD & EXPERT

PERSONAL SUMMARY

I have a Ph.D. in Pharmacy from Uppsala University and more than 25 years of experience from various roles in research, government, industry organization and companies. I have worked as a specialist and manager with a focus on scientific and regulatory issues for herbal medicines and food supplements. It covers areas such as product development, quality, safety, efficacy and product information including marketing.

FIELDS OF EXPERTISE

- Regulatory affairs
- Medical affairs
- Herbal medicinal products
- Food supplement

SPECIALIZATIONS

- Consulting and education
- New products (quality, safety, efficacy and product information)
- Evaluation of the documentation
- The difference between food supplements and medicine (classification, regulations, labeling marketing etc)
- Regulatory affairs strategy
- Labeling and marketing regulation
- Health claims regulation

CONTACT:

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www.catchwell.se

CatchWell
ESTABLISHED SOLUTION

RELEVANT WORK EXPERIENCE

CEO, FOUNDER AND PH.D. (PHARM)

CatchWell AB | 2019 -present

CatchWell offers consulting, scientific and regulatory affairs expert services as well as information and education for food supplements and herbal medicinal products. We make it easier for companies that handle self-care products, to comply with regulations, to make evidence-based decisions, and to provide safe and quality products to the consumer that create opportunities for the company.

CHIEF MEDICAL & REGULATORY OFFICER

Bringwell AB | 2012 - 2018

Participated as an active member of the executive management team to develop and implement the strategy and vision of the company with the respect to regulatory and medical affairs. Established a new Nordic department of medical, quality and regulatory affairs for pharmaceuticals, food supplements, sport nutrition and cosmetic. Managing 3 direct reports. Provided scientific and regulatory expertise in support of business development activities. Ensured that labeling, marketing, advertising is conducted in a manner that is in full compliance with all pertinent regulations. Reviewed new / updates to regulatory guidance(s) and implemented programs to support compliance and member in the HACCP-group. Maintain key relationships with authorities and other stakeholders. Identified applicable standards and regulatory, safety and quality requirements early in the new product development process.

REGULATORY AND SCIENTIFIC EXPERT

Svensk Egenvård | 2007 - 2012

I gave support and advice to approximately 80 companies in regulatory and scientific issues. Further I raised awareness of and developed strong advocacy for the difference between medicinal products and food supplements with key opinion leaders, authorities, industry and health professionals by cultivating collaborative relationships.

- Gave support and advise in the scientific, regulatory and strategic issues and about quality and safety of medicinal products and food supplements
- Responsible for the newsletter ”Regulatory Report” to paying subscribers from companies, pharmacies and health food stores
- Responsible for the development of national industry guideline for safe food supplements to consumers and guideline for safe sport and dieting products to consumers
- Development of certification and certification criteria
- Responsible for answering referrals and other communication with authorities
- Responsible for matters relating to health claim regulation
- Responsible for working committee within Svensk Egenvård
- Lecturer
- Information and education to the public, pharmacy, grocery, authorities, etc
- Knowledge of regulation relating to labelling and advertising
- International cooperation through AESGP and EHPM

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ACHIEVEMENTS:

- Established a new Nordic department of medical, quality and regulatory affairs for pharmaceuticals, food supplements, sport nutrition and cosmetic.
- Worked hand-in-hand with marketing team to ensure that all labeling, marketing, advertising was conducted in a manner that was in full compliance with all pertinent regulations.
- Participated and identified applicable standards and regulatory, safety and quality requirements in all phases of the new product development process.
- Development of two national industry guidelines; Safe food supplements to consumers and safe sport- and diet products to consumers. Development of certification and certification criteria.
- Published a guidance about how to make nutrition and health claims for food supplement.
- Educated pharmacy executive managements regarding regulation for food supplements.
- Participated in public affairs to increase branch visibility and to enhance new and existing business opportunities.

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ASSESSOR

Medical Products Agency | 2004 - 2007

Regulatory affairs. Review of the chemical and pharmaceutical documentation before approval as well as variation and renewal applications. Participated actively in working groups within the EU. Participated actively in the work with new regulations and guidelines. Worked with information to the public, industries, health care and governments.

PH.D.

Medical Products Agency | 1995- 2001

Thesis; Studies on Cytotoxic and Neutrophil Challenging Polypeptides and Cardiac Glycosides of Plant Origin, 2001.
Independent research in natural products, protein chemistry, structural investigation, in-vitro studies (leukocytes, cell lines and cancer cells from patients).Teacher in several courses in pharmacognosy. Supervised, encouraged and instructed students. Planned and directed laboratory work in biotechnology

ACADEMIC HISTORY

PH.D. (PHARM)

Uppsala University | 1995- 2001

SCIENTIFIC PUBLICATIONS

- Small, Novel Proteins from the mistletoe Phoradendron tomentosum exhibit highly selective cytotoxicity to human breast cancer cells. Cell Mol. Life Science 60:165-175, 2003.
- The effect of sesquiterpene lactones on the release of human neutrophil elastase. Biochem. Pharmacol. 65:897-903, 2003.
- A neutrophil multitarget functional bioassay to detect anti-inflammatory natural products. J. Nat. Prod. 65:32-41, 2002.
- Cyclotides- a novel type of cytotoxic agents. Molecular Cancer Therapeutics 1:365-369, 2002.
- Selective cytotoxicity evaluation in anticancer drug screening of fractionated plant extracts. J. Biomol. Screen 7: 333-340, 2002.
- Cytotoxicity of digitoxin and related cardiac glycosides in human tumour cells. Anti-Cancer Drugs. 12: 475-483, 2001.
- Seven novel macrocyclic polypeptides from Viola arvensis. J. Nat. Prod. 62: (2) 283-286, 2001.
- Fractionation protocol for the isolation of polypeptides from plant biomass. J. Nat. Prod. 61: (1) 77-81, 1998.
- Inhibitory activity of a series of coumarins on neutrophil elastase secretion induced by platelet activating factor (PAF) and the chemotactic peptide fMLP. Pharm. Pharmacol. Lett. 8: 144-147, 1998.

OTHER PUBLICATIONS

- Regulatorisk Rapport, 2010- 2012
- Praktisk Guide – and använda sig av närings- och hälsopåståenden, enligt (EG) nr 1924/2006 (2012)
- Säkra sport- och viktminskningsprodukter till konsument (Branschriktlinje, 2012)
- Säkra kosttillskott till konsument (Branschriktlinje, 2009)

POSITION OF TRUST

- Board member of the pharmacognosy section 2011- 2014, Apotekarsocieteten
- Council for Market Supervision 2012- 2013, Svensk Egenvård
- Swedish EU- delegat HMPWG, EMA.