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PRESS RELEASE

LINK Medical expands its regulatory services team, strengthening its IMPD & CMC capabilities

OSLO, Norway, May 03 2021 LINK Medical, the Northern European clinical research organization (CRO), today announced the expansion of its regulatory team with the recent appointment of new regulatory directors in Norway, Sweden and Denmark. This growth further builds upon the company's existing capabilities in early development regulatory strategies including Investigational Medicinal Product Dossiers (IMPD), particularly focused on the Chemistry, Manufacturing and Controls (CMC) section. The strengthened capabilities introduced by these new directors assist companies in achieving compliance with EU regulations that ensure clinical trial approval and patient safety.

The regulatory team offers strong expertise that supports customers within the early clinical development stages. This includes regulatory strategies, GAP analysis, IMPD and CMC support, both for biologicals and non-biologicals, – The appointment of new regulatory directors enables LINK Medical to build an even stronger regulatory position in the Nordics, whilst also offering expertise that can cross borders and support customers globally. LINK Medical has one of the largest regulatory affairs team in the Nordics and today offers a stronger than ever full-service regulatory team. Both large and small biotech/Medtech and pharmaceutical companies can get the full regulatory support regardless of the development phase they are in.

> *"This expansion of our in-house expertise, particularly in IMPD CMC regulatory affairs, illustrates LINK Medical's dedication to the market success of our clients' products."*
> *-Marianne Holst*

Marianne Holst, Executive Vice President of Regulatory Services at LINK Medical, says:
"We are thrilled to build upon our regulatory services with the addition of Lone, Hilde and Kristine to support our customers in the Nordics and beyond. This expansion of our in-house expertise, particularly in IMPD CMC regulatory affairs, illustrates LINK Medical's dedication to the market success of our clients' products."

Lone Dyrby,
Director Regulatory,
Denmark

Kristine Nygren,
Director Regulatory,
Sweden

Dr. Hilde K Holme,
Director Regulatory,
Norway

Lone Dyrby, Director Regulatory, Denmark
Lone has over 20 years' experience within Regulatory CMC, working extensively within biologics. Lone has a MSc in pharmacy and a diploma in leadership. Lone has been part of the Danish team since in October 2020. Prior to that, she had various positions in the pharmaceutical industry as Regulatory CMC specialist and Head of Regulatory Affairs and in the Danish Medicines Agency as CMC assessor of biologics. Lone has extensive experience within Regulatory CMC worldwide.

Kristine Nygren, Director Regulatory, Sweden
Prior to joining LINK in January 2021, Kristine's expertise included 20 years of experience within Regulatory Affairs. She has worked with Pharmaceuticals, Medical Device, and In-vitro diagnostics - with both Global- and European focus. Kristine has also over 10 years of leadership experience from various management positions in the Pharmaceutical Industry and at the Department of Product information at the Medical Product Agency in Sweden.

Dr. Hilde K Holme, Director Regulatory, Norway
Hilde holds a PhD in Biotechnology and has 25 years of experience from the pharmaceutical industry within research, quality control, quality affairs and regulatory affairs, working extensively within all aspects of regulatory CMC. She has been working in small and large pharmaceutical companies with bringing products from the development phase to commercialization in global markets, as well as lifecycle management of commercial products. Hilde has over 15 years of leadership experience from various management positions, locally and globally. She joined LINK on 1 January 2021.

About LINK Medical

LINK Medical is a full-service contract research organization (CRO) providing product development services for the pharmaceutical and medical device industries across Northern Europe. We offer a well-integrated local presence in the Nordics, UK, and Germany. Reaching from early phase development to post-marketing, we have over 200 employees providing expert guidance across every aspect of a project – all from ONE source. Our promise is to improve and accelerate your product development through transformative methods, active communication, and optimal solutions. As a strategic partner, we provide expert competence and technology to enable evidence-based decision-making that supports the delivery of superior clinical outcomes.

For further information on LINK Medical visit www.LINKMedical.eu

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