STARODUB

Experts in Regulatory Affairs

Valentyna Starodub, PhD
Founder, CEO

STARODUB

Outline

- General introduction to STARoDub
- Medical devices

Who we are

- STARoDub is a service provider in regulatory affairs.
- We are:
  - Reliable & Efficient
  - Flexible & Knowledgeable
  - Well organized & High performance

- STARoDub BV was founded end of May 2014
- The name of the company originates from *OLD OAK,* which is symbolizing the wisdom, purity, strength and growth.
- 15 Employees
- 10 active clients
- Quality Management system (QMS) is in place
- ISO 9001 compliant

STAR DUB

Our Mission, Vision, Values

Our Mission

We bring

S trategic
T timely
A ccurate
R egulatory
S ervices

Our Vision

Be the first choice

Be a lean and powerful team

Bring the best STAR's TO EVERY COMPANY

Our Values

Reliability/Trust, Team Work, Respect, Personal excellence, Openness

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What we offer

- Regulatory support from early development to late commercialization of human and veterinary drugs based on small & large molecules; combination products and medical devices.
- NEES/eCTD
- Support with regulatory databases (GREAT/GREACE/Register/etc

Our projects

- Regulatory strategies and execution of required actions for site transfers for APIs (steroids and non-steroids) and Drug Products worldwide
- Life cycle management – preparation, submission and approval of variations for pharmaceutical products (European procedures)
- Support with registration activities related to biotech products
- Product summary files, dossier maintenance
- Business architecture of IDMP
- NEES/eCTD
- Registration information databases
- Medical devices – support during development and life cycle management

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Why to choose us

- We have knowledge of pharmaceutical and medical device industry and world-wide registration processes
- We are strong individually and even stronger as a team.
- Our deliverables are qualitative & on time
- We work according to Right First Time principles
- We have good reputation and positive feedback from clients
- We guarantee good value competitive rates for our services

What we are looking for

Are you a pharmaceutical company active with human or veterinary medicinal products or medical devices and are you looking for regulatory service provider?

STARoDub can make a difference and be your valued partner with registration of products you develop.

Interested?

Let’s make an appointment today!

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Medical Devices and Combination Products

role of STARoDub as regulatory service provider

Erwin Waas, Ph.D.

STAR DUB

What we can

- Regulatory Strategic support
  - Medical Devices, InVitroDiagnostics
  - Combination products (Drug-Device / Device-Drug)
- Regulatory execution
- Be your contact with competent authorities
  - Notified Bodies
  - Agencies world wide

What we offer

- Compliance to regulations and agency expectations
  - Device Classification and Route of Conformity;
  - Risk Management (FMEA / ISO 14971)
  - Quality Management (GLP, GMP, GCP, ISO 13485)
  - Design verification by testing and reporting (DHF)
  - Pre-clinical and Clinical support;
  - Labeling

- Technical file/Design dossier
  - Make use and explain (International) Standards;
  - Self-certification and /or Submissions and Registration;
  - On the market / product life-cycle support

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What we seek

You

- in need of:
  - a knowledgeable partner on regulatory compliance
- having:
  - a product development that needs to go to the next level
- wanting to
  - understand the value of the data you have
- eager to:
  - get your product to the market first time right

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Service conditions

STARoDub operates

- As an expert team (ISO and GxP-trained)
- With First-Time-Right strategy
- Cooperatively with the customer
- With realistic timelines and cost-estimates
- In accordance to GxP and ISO 9001, ISO 13485 (QM), ISO 14971 (RM)
- To better you operation and seeking for continuous improvements


WHO?
WHOM?
WHEN?
WHOSE?
QUESTIONS
HOW?
WHAT?
WHERE?
WHICH?
WHY?