Regulatory Affairs, Quality Assurance
and Pharmacovigilance

RegulaTOP

consulting since 2009

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REGULATOP
Cinzia Boldarino

OUR MISSION

Dear Colleague,
My name's **Cinzia Boldarino**, I'm the founder of **Regulatop**, a Regulatory Affairs and Pharmacovigilance Consultancy focused on Drug Products (both **human and veterinary**) and **Medical Devices**.
The Team hosts seasoned experts together with younger profiles. With this mix of energy and experience, we can follow Projects in a very prompt, tailored and accurate way.

Our **Quality System** helps us to face Companies' needs in a very pragmatic way, having in mind the very basic needs within the Pharma Industry.
Besides our professional inputs, we offer **customized** training sessions to enable Companies develop their own Regulatory and Pharmacovigilance culture.

HUMAN AND VETERINARY DRUG PRODUCT

- Marketing Authorization submission strategy in complex scenarios
- Feasibility studies
- Due diligence and strategic support on companies/portfolio acquisition
- Due diligence on registration dossier
- Marketing Authorization submissions, Variations and Renewals (for Decentralized/MR and National procedures)
- Full CMC expertise, human and veterinary, EU and USA
- Technical writing (mod. 2.3 and mod. 3, IMPD)
- Medical writing (modules 2.4, 2.5, 2.6, 2.7 and translations IT-EN and EN-IT)
- Product Information writing
- Start-up of a pharma company (Italy)
- Advice on Regulatory department organization
- Regulatory Intelligence
- Full regulatory support on Italian Marketing Authorizations:
    - SIS code and CUA applications
    - Digital domicile and certified email
    - Local Representative and Concessionario notifications
    - Marketing Authorization applications and maintenance
    - eCTD publishing
    - Marketing Authorization tranfers
    - AIFA FrontEnd portal management
    - Digital signature recognized on FrontEnd
    - Promotional materials and Scientific Information
    - Congresses
    - Farmastampati, Bozen Databank, Compendia, local OJ publication
    - Traceability related tasks (anti-counterfeiting)
    - Proxy and Digital domicile towards AIFA
    - CPP request (Certificate of Pharmaceutical Product)
    - Decrees retrieval at AIFA (Rome)
    - Price and Reimbursement (in partnership with local experts)

MEDICAL DEVICES

- Proxy towards Italian Ministry of Health
- Support from feasibility analysis to CE marking
- Italian databank: registration and maintenance (Manufacturers and Medical Devices)
- Promotional Materials of Medical Devices: set-up, review, submission till approval

FOOD SUPPLEMENT AND FOOD FOR SPECIAL MEDICAL PURPOSES

- Notification onto Ministry of Health databank
- Free sale certificates

OUR SERVICES

Pharmacovigilance

MEDICINAL PRODUCTS

- Setting-up of Pharmacovigilance Quality System for a Marketing Authorization Holder of a medicinal product
- Providing EU QPPV and Deputy
- Writing Risk Management Plan
- Writing Safety documents like SOPs, PSMF, PSUR, SDEAs, PVAs
- Covering internal Company's roles e.g. Local Safety Officer and Deputy
- Pharmacovigilance in Italy:
    - Local contact of pharmacovigilance
    - Local Literature Screening
    - Writing/translating Educational Materials and submitting for approval (Risk Minimization Measures)
    - Writing Direct Healthcare Professional Communications
- Pharmacovigilance for homeopathic products

MEDICAL DEVICES

- Performing Vigilance and Surveillance tasks related to Medical Devices (Italy)

OTHER

- Performing NutriVigilance
- Performing CosmetoVigilance
- Submission of Adverse Events onto databank Vigierbe

OUR SERVICES

Quality Assurance

Training courses

QUALITY ASSURANCE

- Local QA support to a Marketing Authorization Holder (GDP and GVP):
  - Covering the role of Local QA
  - Drafting GxP documentation (Policies, SOPs, working instructions, manuals…)
  - Managing local medicines Shortage
  - Managing local medicines Recalls
- Setting-up a GDP and GVP Quality System
- Auditing (GDP, GVP) for both medicinal products and Medical Devices

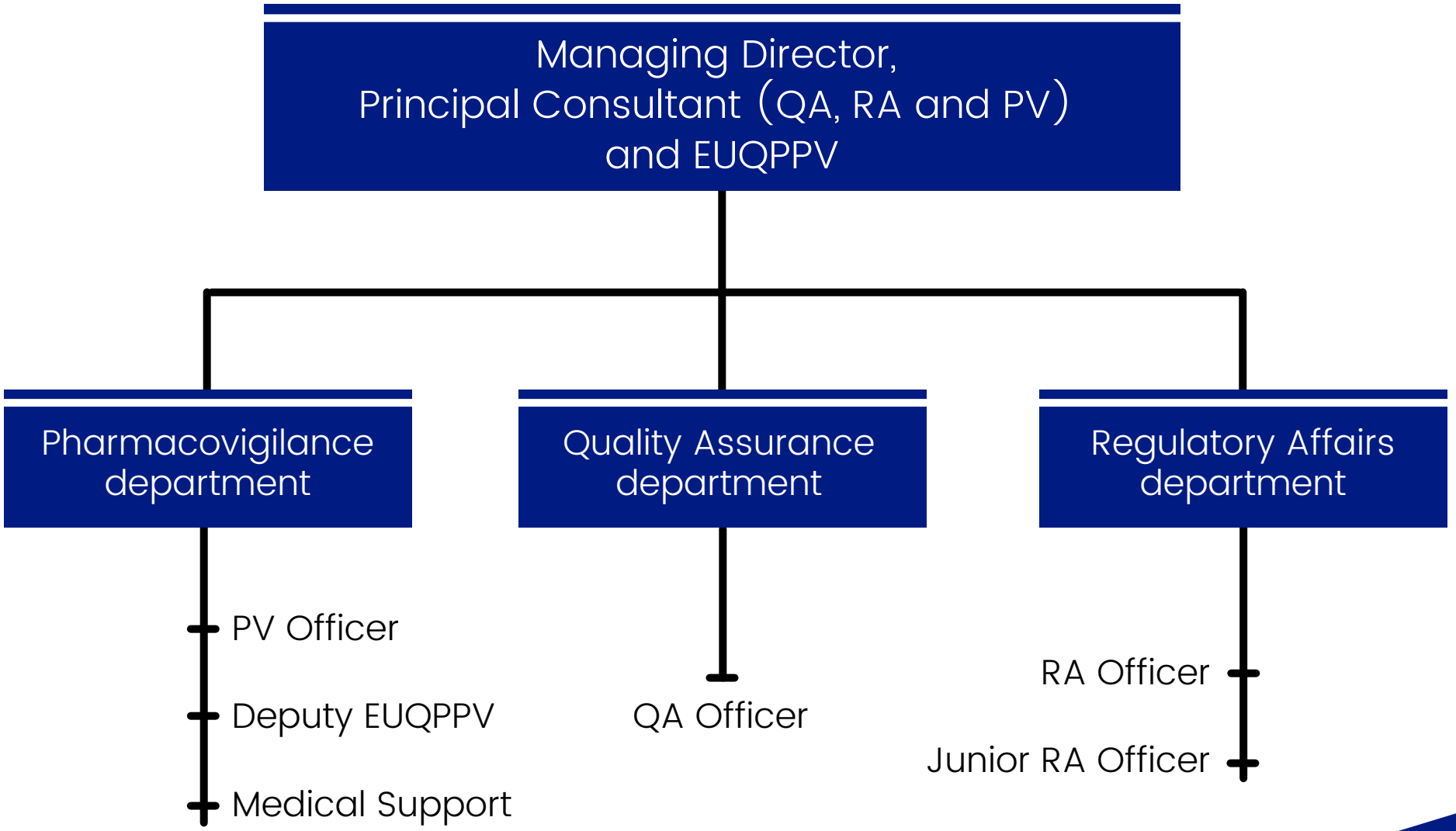
TRAINING COURSES

Regulatop provides training courses as follows:

- Individual tailored training on specific regulatory, pharmacovigilance, quality topics
- Company training on regulatory, pharmacovigilance, quality topics, e.g.:
  - PV training to MAH employees, Sales Force
  - Cases management
  - Specific PV operational tasks

Training can be performed online or vis-a-vis and under tailored plans.

WHO WE ARE


Managing Director,
Principal Consultant (QA, RA and PV)
and EUQPPV
Pharmacovigilance department
Quality Assurance department
Regulatory Affairs department
PV Officer
Deputy EUQPPV
Medical Support
QA Officer
RA Officer
Junior RA Officer