ALBERTO CATAPANO

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HEADLINE SUMMARY

Over 15 years in regulatory affairs, I diversified my experience by expanding my skills and competencies in pharmaceutical products categories (OTC & prescription medicines, medical devices, food supplements, cosmetics). Thanks to the specialized training and certification in Project Management (PMP®) in 2017, I had the opportunity to manage several corporate projects with high technical complexity (e.g., Post M&A integration project, new products, technology transfers, re-formulation, new productions), involving several teams from different company departments and external partners. I'm managing three qualified people in regulatory affairs. Problem-solving and communication skills are my personal strengths. I'm also passionate about training and, for a long time, I'm cooperating as a speaker in two master classes of regulatory affairs (the University of Pavia and the University of Novara) sharing my experience and knowledge.

PROFESSIONAL EXPERIENCES

January 2018 – present **NTC Pharma S.r.l., Via Luigi Razza 3, 20124 Milano**

Regulatory & Project Coordinator Manager

Key responsibilities:

- Leading M&A project integration plan for acquired products and technology
- Supporting the Chief Regulatory Office to manage corporate regulatory projects for medicinal products, medical devices, food supplements, cosmetic products.
- Ensuring compliance with regulatory bodies, managing timelines, keeping records, and gathering project resources.
- Supporting internal functions (BD&L, Alliance, Operations) for contractual, commercial, operational aspects relating to corporate products
- Supporting external Partners for the launch and maintenance of licensed products

October 2015 – December 2017 **Proge Farm Srl, Largo Donegani 4/A, 28100 Novara**

Regulatory Compliance Manager

Key responsibilities:

- Overseeing the entire development process for new health products and treatments.
- From the initial idea through the market sale.
- Creating status reports for management, ensuring compliance with regulatory bodies, managing timelines, evaluating the project risks, specifying project plans, establishing work schedules, keeping records, and gathering project resources

May 2013 – September 2015 **Proge Medica Srl, Largo Donegani 4/A, 28100 Novara**

Regulatory Affairs Specialist & Project Coordinator

Key responsibilities:

- Variations, Renewal, New MAA through national or centralized procedure.
- Scientific Advice (National Competent Authority or EMA);
- AIFA Pharmacovigilance Inspections.
- Request for a CEP (new application or revisions) to EDQM.
- Medical Devices: ISO 13485:2012 certification and Technical File management;
- Food Supplements: Claims and regulatory advice.
- Scientific Services and Marketing Support ensuring regulatory compliance.
- Third Contract Parties Management;
- Standard Operating Procedures for GMP and GVP
- Strategic project cross- functions coordination

January 2013 – April 2013 **GlaxoSmithKline S.p.A., via Zambeletti snc, Baranzate Milano**

Regulatory Affairs Specialist

- Regulatory Support for OTC Business Division products (medicinal products, cosmetic products, medical devices, food supplements).

June 2010 – December 2012 **Bracco S.p. A., via XXV Aprile 4, San Donato Milanese, Milano**

Regulatory and Medical Affairs Specialist

- Regulatory Support for OTC Business Division products and for corporate projects (e.g. pharmacovigilance inspection, Non Clinical Scientific Advice, Request for a CEP, Corporate ASMF update, CE mark procedure for ophthalmological medical devices - Alfa ® eye drops line)

EDUCATION AND TRAININGS

January 2009 – December 2010 **University of Pavia**
Second Level Master's degree in Regulatory Sciences "G. Benzi"
Final work title "*Regulatory Assessment of an antipandemic vaccine product: Focetria® Novartis*"

September 2003 – October 2008 **University of Napoli "Federico II" Faculty of Pharmacy**
Pharmacy Master's Degree
Final work title "*Pharmaceutical European Legislation and Regulatory Agencies*"
Final Grade: 102/110

February – July 2007 (ERASMUS) **Universitat de Barcellona – Catalunya Spain**
Title of exam awarded: Marqueting Fàrmaceutico
Votation : 28/30
Dissertation Title "*Trabajo: Plan de Marqueting : Aliskirien – Novartis* "

COLLABORATIONS AND CERTIFICATIONS

- Collaboration as **speaker** with the Master of University of Pavia: "*Regulatory Affairs Sciences -G. Benzi*"
- Collaboration as **speaker** with the Master of Faculty of Pharmacy – University of Piemonte Orientale - Novara: "*Regulatory Affairs*"
- **Business Plan Certification** "Project START 2013" issued by Lombardia Region in collaboration with Milan Commercial Chamber (July 2013)
- **Project Management Institute member,** Northern Italy Chapter (July 2016)
- **Project Management Professional (PMP ®) Certification:** The PMP ® is the gold standard of project management certification. Recognized and demanded by organizations worldwide, the PMP validates your competence to perform in the role of a project manager, leading and directing projects and teams.
- **Project Management Education (40 hr)** covering project integration, scope, time, cost, quality, human resource, communication, risk, procurement and stakeholder – Attuare s.a.s (June 2016)

LANGUAGES AND IT SKILLS

LANGUAGES: Italian, mother tongue**,** English: C1; Spanish: B2.
IT COMPETENCES: Microsoft office package.
HOBBYS: surfing, skiing, cooking, travelling