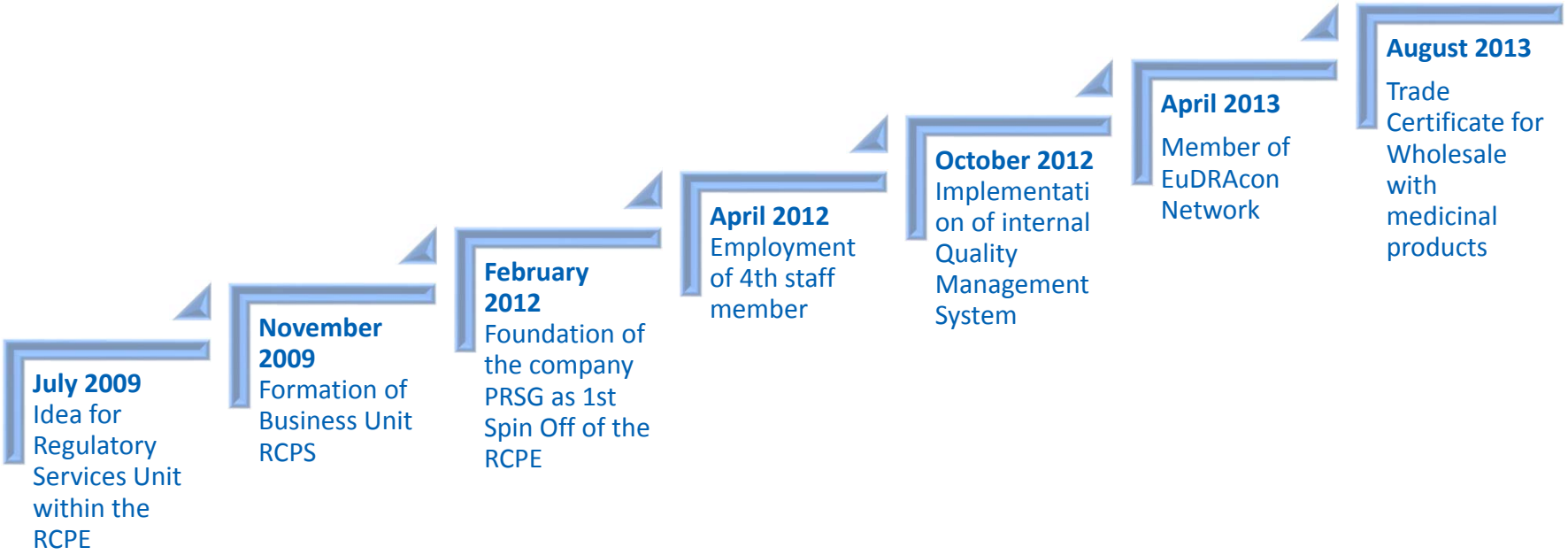
Pharmaceutical and
Regulatory Services GmbH

Regulatory Work
from Start to Finish.

Pharmaceutical and Regulatory Services GmbH

What it is all about…

Company History



Product Categories & Services

- Human / Veterinary Medicinal Products
- Medical Devices Class 1
- Food and Nutrition
- Cosmetics / Wellness Products

- Consulting
- News & Information Services
- Dossier Creation
- Dossier Maintenance
- Applications

Consulting – Regulatory Guidance

- **Detailed Knowledge**
  - European regulations and directives
  - National law
  - Experience with authorities
  - Scientific education and background

- **Expertise**
  - Strategic and regulatory advice for national / international issues
  - Choice of appropriate application procedure
  - Advice for application for SME status
  - Advice for application for scientific advice
  - Preparation and attendance at meetings with authorities

Consulting – Regulatory Guidance

- **Support**
  - Evaluation and preparation of marketing authorisation dossiers
  - Life Cycle Management
  - Quality related issues
  - Update and revision of product informations
  - Pharmacovigilance

- **Advice**
  - New development concepts
  - Non-Clinical and Clinical Issuses
  - Health Claims

News & Information Services

- **PRSG Newsletter**
  - Published monthly
  - Subscription includes consultation period
- **Literature Research**
  - Conventional online databases
  - Literature retrieval as PDF file or hard copy
- **Trainings**
  - Internal / External trainings

Dossier Creation

- **Evaluation of new / existing regulatory documents**
- **Preparation of complete dossier or individual modules**
- **eSubmissions**
  - (e)CTD
  - NeeS
  - vNeeS
- **Preparation of expert statements / overviews**

Dossier Maintenance

- **Life Cycle Management**
  - Initial application
  - Variations, Renewals
  - Sunset clause
  - Processing deficiency letters

- **Update / revision of product informations** (using actual QRD templates)
  - SmPC – PIL – labeling
  - Readability Testing (subcontracting)

- **Preparation of Periodic Safety Update Reports**

Applications

- **Procedures**
  - National procedure
  - Decentralised procedure
  - Mutual recognition procedure
  - Centralised procedure
- **Application types**
  - Initial application (Full, generic, hybrid, informed consent, bibliographic,…)
  - Variations, Renewals, Follow-up activities
- **Monitoring deadlines**

Experience	• Essential factor for pharmaceutical regulatory consultants • Great value upon the qualification and educational background • Experienced in strategic planning and implementation of regulatory concepts • Preparation and submission of regulatory documents
Ressources	• Team of 4 • Cover of peak loads • Versatile regulatory affairs managers
Skills	• Highly educated and trained staff • Regular attendance of specific trainings • Self-study of current regulations, directives, national laws
Individual Solutions	• Costumized services on modular basis • Strategy dependent on internal timelines, business plans, budget and launch dates • Short-term or long-term cooperation
Information Technology	• Use of highest electronic standards • Consistent update of IT-system • Support of international electronic submission standards

Contact

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Thank you very much

for your attention!