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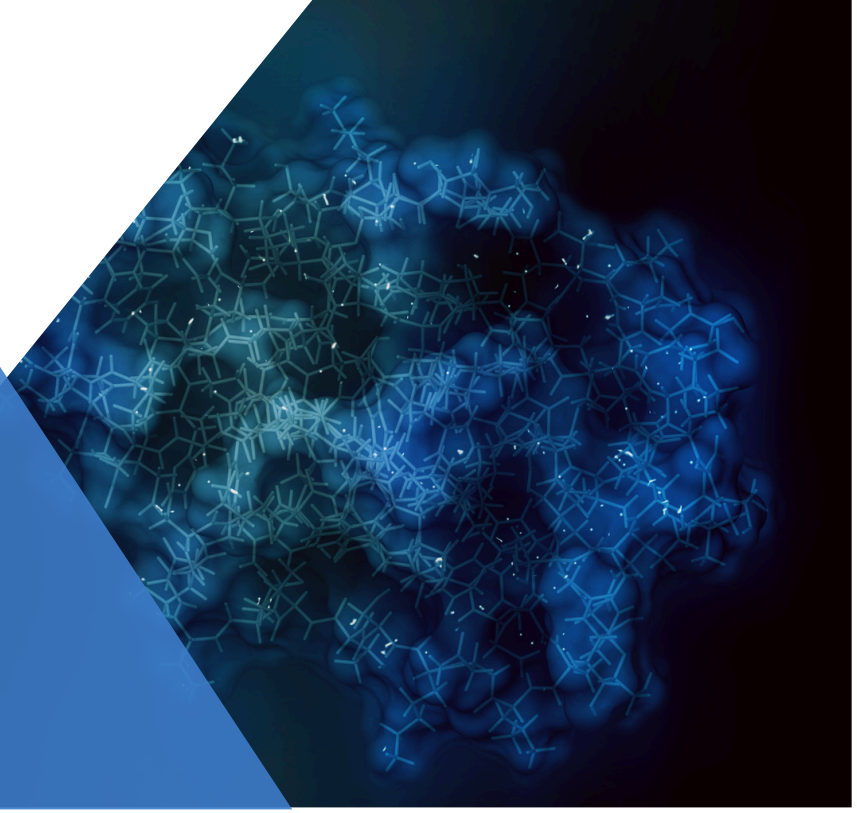

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Services at a Glance

Strategy Support

- Advisory services
- Industry and agency perspective
- Gap analysis
- Market entry strategy

Submission Writing

- Planning and preparation
- Authoring and review
- Access to templates
- Electronic submissions

Regulatory Intelligence

- Updates and alerts
- Tracking and monitoring
- Newsletter and publications
- RA intelligence database
- Networking and collaboration

Training Support

- Regulatory requirements
- Regulatory processes
- Best practices
- Workshops and webinars

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SUBSCRIPTIONS

Services	Lite	Pro	Pro Plus
Regulatory Strategy Support	Up to 25 hours per year	Up to 50 hours per year	Up to 100 hours per year (50 of which can be ex-FDA/Agency SME)
General Regulatory Support (submission, drafting, change assessments)	Up to 250 hours	Up to 500 hours per year	Up to 800 hours per year
Regulatory Intelligence	Monthly Regulatory Intelligence Newsletter	Monthly regulatory intelligence newsletter	Individualized responses to team questions specific to new regulations
Access to NPG Library	Webinars, case studies, and white papers	Webinars, case studies, and white papers	Webinars, case studies, and white papers
Access to NPG Regulatory Templates	Standard Template Access IDE, IND, CTD, Technical Document, 510k, Labeling, QOS	Standard template access IDE, IND, CTD, technical document, 510k, labeling, QOS	Additional template access: PMA, CER, PMS, NDA, BLA, ANDA, RMP, PSUR, pharmacovigilance plan
Hosted, Virtual Lunch-and-learn (30-45 mins)	Two (2) stock lunch-and-learn per year	Two (2) stock lunch-and-learn per year	Two (2) stock or customized lunch-and-learn per year (can be ex-FDA/Agency trainer if requested)
Strategic/Process Planning Workshop			One (1) workshop per year included (ex. for original PMA, 510k, NDA, BLA)

Programs through Network Partners Group requiring more hours than the subscription provides are available on a separate scope of work. Please contact NPG to discuss any of your regulatory needs.

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NPG RA International Experience

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- Australia
- Brazil
- Canada
- China
- Columbia
- Ecuador
- Europe, the Middle East, and Africa (EMEA)
- India
- Japan
- Kuwait
- Latin America (LATAM)
- Mexico
- Middle East
- South Korea
- Switzerland
- Taiwan
- Thailand
- UK

NPG International Regulatory Solutions Project Type

- Gap analysis and remediation of existing documentation
- 510k and PMA equivalent submissions/Product dossier submissions
- Regulatory queries, strategy, and compliance
- Regulatory CMC strategies and documentation prep for product development and commercialization
- Pre-approval and post-approval (life cycle management) activities (including HIV, oncology drug products)
- Post-approval variations, preparation, and submission of regulatory documents (including CMC variations)
- Re-registrations, notification-only submissions, and file update
- Leveraged EU MDR to create, edit, and review technical documents for various countries
- Declarations of conformity
- Product Licensing, including Health Canada
- GxP compliance activities, quality checks, and documentation of quality procedures.
- CMC, quality inspections, and regulatory guidance
- Marketing approval under Sakigake designation system (Japan).
- Assess acceptability of quality, preclinical, and clinical documentation for submissions, support license remediation, and renewal submissions
- Assist with EU Authorized Representative mandate updates
- Regulatory Labeling compliance
- EUDAMED & EU UDI
- Change in Notified Bodies

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