

ON-DEMAND REGULATORY AFFAIRS SUPPORT



Your Regulatory Lifeline. Ready Whenever You Need It.

Juggling shifting regulations, looming deadlines, and surprise project surges can feel like walking a tightrope—one misstep means costly delays or compliance headaches.

NPG On-Demand gives you expert regulatory support across the full spectrum of RA needs - from strategy and planning to submissions and day-to-day execution.

Whether you're navigating market entry, responding to agency feedback, or managing routine filings, we plug in exactly where you need us. Consider us your in-house regulatory team—without the overhead—keeping your progress steady, your risks low, and your focus where it matters most.

Why Choose NPG?

- **Expert Access, Anytime:** Get direct access to a full team of seasoned regulatory experts. Whether you need strategic guidance or a quick answer, our experts are just a call away.
- **Scalable Support, No Extra Headcount:** Regulatory demands fluctuate, but your team size doesn't have to. We step in when workloads surge, so you stay on track without the hassle of hiring.
- **On-Demand Regulatory Assistance:** From day-to-day needs to strategy to ever-changing compliance and regulatory intelligence.

Services at a Glance



Strategy Support

Seasoned advisors with deep agency and industry perspectives to conduct gap analyses, refine your regulatory roadmap, and launch market-entry strategies that align with your business goals.



Submission Writing

Offload your next filing to our expert team: we'll handle planning, authoring, review, and electronic submissions, leveraging proven templates to fast-track approvals.



Regulatory Intelligence

Plug into a real-time stream of updates, alerts, and in-depth newsletters, backed by our RAintelligence database and collaborative network, to stay ahead of every regulatory shift.



Training Support

Elevate your team with interactive workshops and webinars on regulatory requirements, processes, and best practices, building compliance expertise that drives results.



Professional Project Management

Tap into certified PMPs to drive execution, manage timelines, and keep your packaging initiatives on track and on budget.

Here's How It Works



Schedule a Call

Connect with our team to talk through your regulatory challenges, goals, and what support looks like for you



Choose Your Plan

Pick the tier that matches your workload and budget. Get the right level of support at the right time or just when you need it.



Activate Your Experts

Once you're set up, our RA specialists jump into action—strategy, submissions, intelligence, templates—handling every detail so you can stay focused on your next milestone.

CONTACT NPG TO GET STARTED

574-377-7151

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WITH FLEXIBLE TIERS, YOU GET EXACTLY WHAT YOU NEED - NO MORE, NO LESS.

Services	Pro	Pro Plus	Platinum
RA Hotline Your direct line to expert SME support when you need it most.	25 hours of SME support per year	50 hours of SME support per year	100 hours of SME support per year (50 of which can be ex-FDA/Agency SME)
Regulatory Taskforce Extra hands and expertise for submissions, authoring, revisions, and more.	Up to 250 hours per year	Up to 500 hours per year	Up to 800 hours per year
Regulatory Intelligence Buzz Monthly intel briefs and answers to your compliance questions.	Monthly Regulatory Intelligence Newsletter	Monthly regulatory intelligence newsletter	Individualized responses to team questions specific to new regulations
Regulatory Hub Exclusive access to webinars, case studies, and expert resources.	Access to webinars, case studies, whitepapers, and more	Access to webinars, case studies, whitepapers, and more	Access to webinars, case studies, whitepapers, and more
Regulatory Playbook Ready-to-use templates and guidance for global compliance.	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
Lunch & Learn Lounge Virtual sessions to feed your brain.	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)
Blueprint Strategy Session Hands-on planning for big submissions.			One (1) on-site workshop per year included (ex. for original PMA, 510k, NDA, BLA)

Add-Ons

Need even more support? Our add-on services let you customize your NPG On Demand plan with additional expertise, tools, and resources. Get exactly what you need, when you need it.

Packaging Engineering Support

Labeling Support

Quality & Compliance Support