Hannah Edward

Fractional CMC Regulatory Affairs Consultant

Pfizer · Viatris · Allergan · 12+ Years Global CMC Experience

Dublin, Ireland · Remote

EU · US · ROW

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WHO I AM

I help emerging biotech and pharmaceutical companies get their CMC dossier submission-ready — without the overhead of a full-time regulatory hire. With 12+ years of senior CMC experience across Pfizer, Viatris, and Allergan, I bring global regulatory expertise to your most critical submissions on a fractional basis.

RESULTS I'VE DELIVERED

25%	15%	617+	12+
Reduction in PDM update cycle time at Pfizer	Reduction in portfolio maintenance cycle time at Viatris	Regulatory submissions led at Pfizer (2021–2023)	Years across EMEA, US, APAC, Latin America

→ Contributed to CMC post-approval submissions for the COVID-19 vaccine booster programme
→ Successful global submissions across EU, US, Canada, APAC, and Latin America
→ Integrated AI and RegTech tools — Veeva Vault RIM, eCTD authoring, TrackWise — into regulatory workflows

SERVICES

CMC Dossier Readiness
Gap analysis and remediation roadmap for first regulatory submissions

Post-Approval Changes
PACMP strategy and ICH Q12 implementation for post-approval change management

Global Submissions
Coordination across EU, US, and ROW markets with full eCTD capability

CMO/CDMO Oversight
Regulatory compliance alignment with contract manufacturers and development organisations

FLAGSHIP OFFER

CMC Submission Readiness Review

Fixed-scope · 8-week engagement · Senior CMC expertise on demand

Week 1–2 Full CMC dossier gap analysis
Week 3–4 Prioritised remediation roadmap
Week 5–6 Regulatory strategy document
Week 7–8 Final review + 30-day email support

Investment

€6,500

Fixed fee · No surprises

50% on signing
50% on delivery

Contact for pricing

WHO I WORK BEST WITH

Early-Stage Biotech
Preparing for first regulatory submission and needing senior CMC guidance without a full-time hire

Mid-Stage Pharma
Managing post-approval change events or building CMC regulatory capability

CDMOs & CROs
Needing regulatory oversight support for client-facing CMC compliance and submission activities

Ready to get your CMC dossier submission-ready?

Book a free 30-minute discovery call to discuss your regulatory needs.

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