SERVICE OVERVIEW - 2026

Pharma Interim Management - Regulatory Affairs meets certified Project Management

Julius Vincenz Weidlich

Interim Regulatory Program Lead - Pharmaceutical Industry, DACH & EU

The combination that resolves your organization's challenges successfully and efficiently: in-depth Regulatory Affairs expertise across 100+ markets (EU MRP/DCP/CP/NP, APAC, CIS, MEA, LATAM, Greater China) combined with PMP-certified program and portfolio leadership.



Image source: bpncommercial.com

20+

Years in the pharmaceutical industry

9

Years in Regulatory Affairs

8

Years of project & program leadership, PMP-certified since 2024

Julius Vincenz Weidlich - Bad Homburg, Germany - +49 160 9352 3299 - julius.weidlich@wrpa-pharma.eu

WHAT I OFFER

Four Ways to Work Together

Interim RA Management

Operational regulatory ownership, variations, renewals, PSUSAs; health authority liaison in the EU, coordination with local teams and partners across APAC, CIS, MEA, LATAM — flexibly scalable from short-term capacity bridging to full role coverage.

Interim Program/Project Steering

Leading LCM portfolios of up to 20 concurrent projects; critical-path steering, RAID-based risk management, stage-gate governance.

EU Reform Readiness Mandates (incl. Diagnostic Sprint)

Preparing for the new Variations Guidelines (in effect since 15 January 2026) and the EU Pharma Reform 2026-2028; gap analysis and actionable project plans. Entry point via the 2-week Diagnostic Sprint (EUR 5,000 fixed fee).

eCTD v4.0 Project Coordination

Project coordination to prepare for eCTD v4.0 (ICH M8) — recommended from Q1 2027, mandatory from Q1 2028 for new centralised marketing authorisation applications. No technical implementation.

Selected Reference Projects

CMO Change

Supported a manufacturer change for an approved product via a grouped variation. Result: uninterrupted market supply.

Climate Zone IVb Expansion

Closed a stability data gap through a primary packaging change, avoiding a costly reformulation and additional studies.

M&A / Marketing Authorization Transfer

Coordinated global marketing authorization transfers (MATs) following an acquisition, resolving MAH-qualification gaps. Result: transfers completed.

FIT, TERMS & NEXT STEPS

Let's Start a Conversation

✓ Good Fit

Hybrid RA+program mandates, multi-project LCM portfolios, EU-Reform-driven governance needs.

✕ Not a Fit

Purely toxicology roles, permanent employment.



3-12 Months	Available short-term	PMP - TOPRA
Typical mandate duration	Availability	Certification & memberships

Book a free 30-minute introductory call ->

Julius Vincenz Weidlich - Bad Homburg v.d.Höhe, Germany - active in DACH & EU

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