

FIDES REGULATORY AFFAIRS CONSULTANCY

Your Big Next Biggest Collaboration



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FIDES REGULATORY AFFAIRS CONSULTANCY



7-9 SEPTEMBER
NEW DELHI 2026

Bharat Mandapam, New Delhi

BY DHARMI PATEL & HETVI PATEL (FIDES REGULATORY)
DONT HIRE REGULATORY TEAM- HIRE US -EXPERTS.

Introduction



We are Fides RAA offer Pharmaceutical Regulatory Affairs Assistance.

Would like to present our bit of Introduction to you sir, as ready reckoner, whenever you may require such services. Or else, if anyone requires such services, as referral point, I am presenting to you.

Fides RAA regulatory technical expert team is comprised of 16 team members, established in 2015. We specialize in regulatory support and can cater to all your needs.

We would be available @IPHEX 2026, 7 - 9 September, Bharat Mandapam, Delhi, INDIA (4TH Exhibition at iphex)

We are a one stop solution for Pharmaceuticals Regulatory Affairs as niche. Having highest capacity for dossier producing, our team comprise of total 16 people. Among them 11 trained professionals are dedicated to regulatory services only & rest are allied staff or marketing & business development team.

**Understanding
the services
offered by us**



Services Offered:

1. Dossier Compilation and Submission Dossier Conversion (Non-CTD to CTD, ACTD, eCTD, NeeS, Country Specific or Regional Submission) for ASEAN, MENA, LATAM, EU, CIS, AFRICA, GCC and many row markets.
2. CTD dossier writing
3. BA/BE Studies & Clinical Trials
4. Clinical Trial Application in DCGI & BE NOC As per New Amendments from DCGI, INDIA
5. ACTD dossier writing
6. DMF-ASMF writing
7. Analytical Method Validation for Dissolution, Identification, Assay, Related Substances (Impurity) and Residual Solvent. (HPLC- with chromatogram, UV- with spectrum), Impurity Profile Validation



Services Offered:

8. Comparative Dissolution Profile (HPLC- with chromatogram, UV- with spectrum, with calculation of f1 & f2, also with audit trial report).
9. Bio- analytical Validation / Report and Protocol along with ANOVA calculation for BA/BE report, 100 % chromatograph, with reference product images, purchase bill, shipment detail, GLP, GCP certificate
10. Third party Co-ordination for Bioavailability / Bioequivalence / Clinical Trial Studies / Pre-clinical trial studies through well-established study centres for various dosage forms
11. List of countries handling presently : Nigeria, Ghana, Kenya, Rwanda, Uganda, Myanmar, Philippines, Cambodia, UAE, Saudi Arabia, Cameroon, Angola, Niger, Tanzania, Mozambique, Liberia, Madagascar, Burkina Faso, Ethiopia, Togo, Mali, Malawi, Burundi, Botswana, South Africa, Mongolia, Sri Lanka, Bangladesh, Malaysia, Vietnam, Uzbekistan, Tajikistan, Azerbaijan, Kyrgyzstan, Turkmenistan, Armenia, China, Hungary, Iran, Ukraine, Thailand, Romania, Kazakhstan, Indonesia, Georgia, Colombia, Egypt, Yemen, Syria, Russia, Zimbabwe

However, list always doesn't limit to this, we can draft, write, compile & submit to any country for any molecule with any dosage forms



Services Offered:

12. Product information updates (SmPC, PIL and Labelling).
13. Patient Safety Update Report, Pharmacovigilance Report, Risk management Plan
14. Dossier Audit with Risk Assessment grading , & we can provide the solution to provide gap by document preparation
15. Product registration in various countries across the globe
16. Audits and Regulatory compliance
17. GMP /GLP AUDITS
18. 360o Documentation
19. Process Validation Services - for any dosage form & any product type, molecule name, with protocol, report, chromatograph, excel calculation & audit trial report.
20. Pharma Plant setup and Key Project - GMP layout, plant approval, jury question answering, engineering drawings, HVAC setup & qualification
21. Complete SOP documentation & complete IQ, OQ, PQ documentation

Services Offered:

22. eCTD Publishing for Document level and and for Publishing level, DMF CEP, ANDA Submission GCC, & SRA 23. Structured Product Labelling (SPL) Services

24. Expert advice for Regulatory Operations planning / strategy / management like submission attributes, STF file tag, gap analysis, and life cycle operations, document tracking through eCTD checklist & document change history and eValidation troubleshooting with strict adherence to health authority requirements

25. eCTD with Country-wise and client-wise, experienced and qualified team for end-to-end Regulatory Operations service i.e. document level (DLP) and submission level publishing (SLP), additionally 24 x 7 client support (anytime and anywhere)

26. For eCTD services, Fides serve pharma / healthcare industry with all required standards of Regulatory Publishing i.e. tools (PDF toolbox, eCTD Software and eValidator), submission checklist (file naming, leaf title, life - cycle operation), quality review checklist (pre, intermediate and post compilation) etc.



Services Offered:

27. All above services for Pharmaceuticals, Biopharmaceuticals, Biosimilars, Biotechnological, Neutraceuticals Products and also we assist in Cosmetic, Medical device, Herbal medicines, Traditional Medicines, Unani Medicines

28. Query support for all of above type of documents till registration - we are now since last 9 years, & built a trust among over clients, regular visiting CPHI & regularly exhibiting at IPHEX since last 8 years.

29. SOP Preparation- Vernacular SOP, Quality Manual (QM), Laboratory Information File (LIF), Validation Master Plan (VMP), Utility Qualification- HVAC, Water, Air Compressor, Nitrogen etc., Instrument Qualification and Calibration - QC Instrument, Weighing Balances etc, Facility Qualification - DPB, RLA

30. Annual Product Quality Review

31. Continues Process Verification

32. Hold Time Study- Clean Equipment and Dirty Equipment, Product

33. FDCA Application Support- New Mfg. Lic, GMP/GLP, WHO GMP - ONDL ON CDSCO



Services Offered:

34. ONLDS Registration- Firm, Technical Person



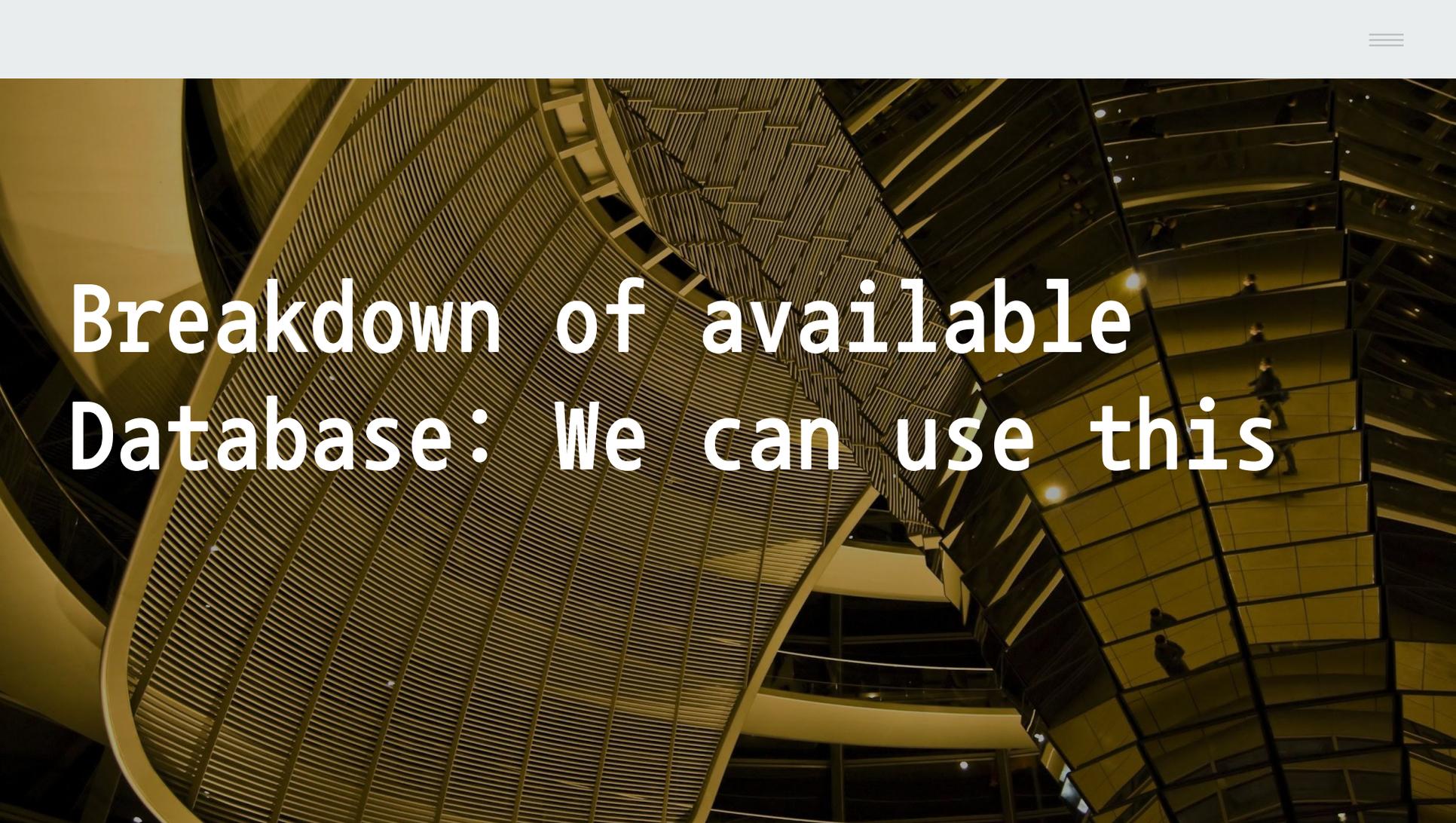
35. GAP Analysis against Revised Sch M and Compliance Support

36. Product- Production and Packaging Risk Assessment

37. Elemental Impurity Risk Assessment

38. Nitrosamine Impurities Risk Assessment

39. DNA Reactive (Mutagenic) Impurities Risk Assessment



Breakdown of available
Database: We can use this

DATABASE



	Stage	Approx data base available	USE
1	NEW COMPILED DOSSIER TILL DATE BY OFFICE(9 YEARS WITH 10 EMPLOYEES ON FULL TIME BASIS MOST OF ARE OF ROW MARKET	1800 ENTRIES ROUGHLY	RAW DATA CAN BE USED TO BUILD NEW DOSSIER STARTS FROM 12000 TO 60000 INR
2	Ready EU, USA , CANADA DOSSIER	2700 ENTRIES ROUGHLY	FOR TECHNOLOGY TRANSFER & READY TO SUBMIT BY MA transfer (Price range from 30000 to 2,00,000 INR)
3	DMF OPEN PART	6000 ENTRIES ROUGHLY	FOR USE IN DOSSIER
4	AMV(ASSAY, RS, DISSOLUTION, RESIDUAL, IMPURITIES, BIO-AMV FOR BE)	4500 ENTRIES ROUGHLY	METHOD TO BE USED IN YOUR NEW AMV DOCUMENT
5	CLINICAL TRIAL DATA & BE	148 ENTRIES ROUGHLY	RAW DATA CAN BE USED TO BUILD YOUR NEW DOCUMENT

ASK TO US FOR READY EXCEL SHEETS



Specialize in "Compilation, Review,
Drafting of DOSSIER, BA-BE, AMV, PSUR,
SPL, DMF-ASMF, CDP, PDR (Q8), PVR,
MFR, TT, APQR, eCTD, ASEAN, SPL, eCTD
Software GLOBALLY, GMP WORK, CDSCO,
NOC, COPP, ONDL, EXPORT CONSULTANCY"



IPHEX

7-9 SEPTEMBER | 2026
NEW DELHI

Bharat Mandapam, New Delhi





SOCIAL MEDIA



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Fides Biocare manufacturers & exporters



1. Dhaarmi Patel,
2. Fides Regulatory
3. Fides BioCare



EXHIBITION

IPHEX INDIA – Stand Confirmed, 8–10 Sept 2026

CPHI-INDIA – B8-205 (25–27 Nov 2025)

WHX DUBAI – Visitor (9–12 Feb 2026)

CPHI SEA Bangkok – Visitor (8–10 July 2026)

CPHI AMERICANO – Visitor (2–4 June 2026)



Dhaarmi Patel



Technical Head & Founder

Fides Regulatory Affairs & Export Consultant

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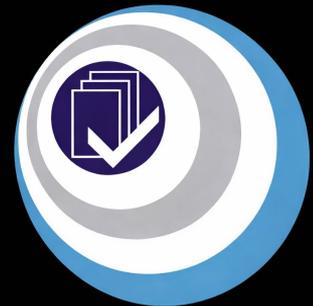
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**Thanking you
and looking
forward to serve
you.**



FIDES RAA

