METINA
PharmConsulting
Global Regulatory Services

Quality and Regulatory Scientific Services for Global Pharmaceutical Industry

METINA Background

Established in 2012, Metina is an Indian company with headquartered in New Bombay, with an affiliate company in Singapore (Metina Singapore Pte Ltd.).

Metina is a pharmaceutical and bio-pharmaceutical consultancy organization engaged in GMP and Regulatory services for small and large molecules across the globe. The company has achieved multiple ANDAs and DCPs approvals, as well as EU GMP certifications for varied dosage forms. The company offers WHO PQP, emerging market regulatory expertise and biosimilars intelligence advice for BRICS-TM markets.

Vision

To be a reliable regulatory and quality partner to the pharmaceutical and bio-pharmaceutical industry by implementing comprehensive, knowledge driven & time bound services, with impeccable work ethics.

Unique Attributes

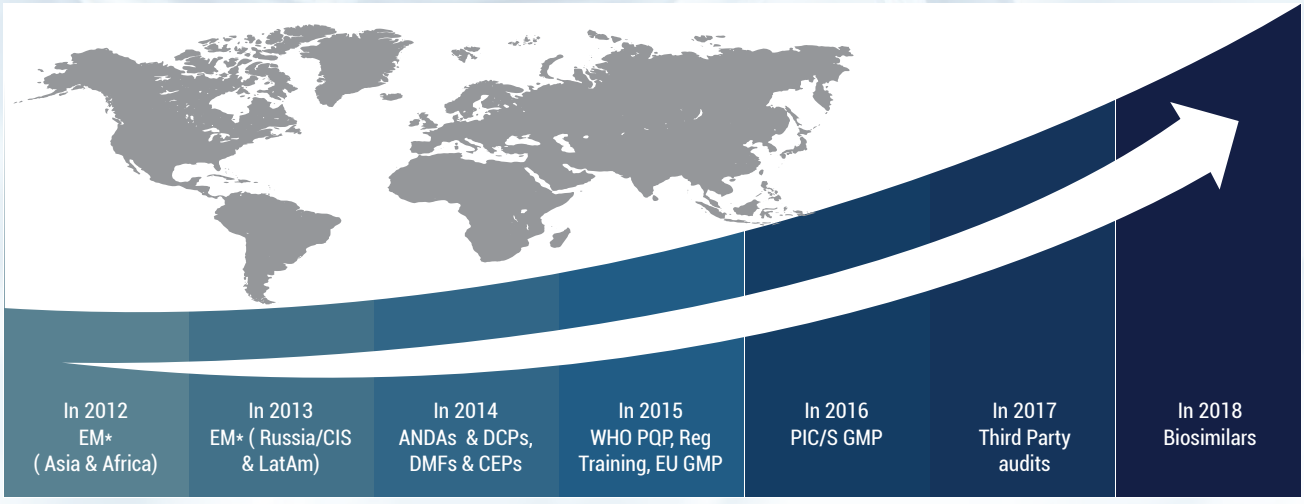
- Compliance to highest ethical standards
- Highly knowledgeable and experienced internal experts
- Time bound project execution
- 100% success for EU GMP and regulatory services
- ANDA filing in full compliance with RTR standards
- Integrated services for regulatory filing in EU via DCP / Centralised / National procedure
- Work in co-operation with client's inherent leadership

Corporate Profile

Name	**Metina PharmConsulting Pvt Ltd.**	**Affiliations**	Metina Singapore PTE Ltd.
Address	901-903, Goodwill Infinity, Sector-12, Kharghar, Navi Mumbai, Maharashtra, India- 410210	**Address**	31, Cantonment Road, Singapore - 089747
Telephone	+91 22 6243 3000	**Telephone** **Telefax**	+65 62244991 +65 62277994
Email **Founder & Director**	hasumati@metinapharmconsulting.com Mrs. Hasumati Rahalkar	**Membership**	Regulatory Affairs Professional Society (RAPS), The Organization for Professionals in Regulatory Affairs (TOPRA)
Business	Comprehensive consultancy services in GMP and Regulatory Field	**Presence**	Global

GLIMPSE OF METINA

BUSINESS GROWTH INDEX



*Emerging Market

ANDA SUBMISSIONS AND APPROVALS

505(b)(2) AND 505(j) ANDA APPLICATION

Development

- Controlled correspondence with CDER, FDA
- PDR review
- Specification review and approval
- Technology transfer protocol and data review
- Pilot & pivotal batches strategic advice
- Manufacturing record review

Scientific Script

- ANDA overall assessment form
- Master Checklist for ANDA
- NDC number reciept
- GDUFA fees
- EIR evaluation
- Respnse to DMF assessment questions
- Labelling formation
- Module 1 package
- CMC data review
- Accurate detailing of Module 3
- Articulation of Module 2.3 and 2.7
- eCTD conversion

ANDA submission & Approval

- Electronic submissions to CDER, FDA
- Prompt resolution of deficiencies to comply refuse to receive decision
- Review deficiencies's response submission
- Action on Complete Response (CR)
- Tentative approval or Final approval letter action
- Submission of labelling

1 — 2 — 3

USDMF

- For Pharmacopoeia and internal quality active substance, DMF development advice
- Writing of CTD-DMF & eCTD submission to CDER, FDA
- Deficiency response for complete assessment review of DMF
- Maintaining Active status of DMF
- Support in major change updates

AT HAND LICENSED ANDAs

Metina has efficiently managed multiple ANDAs submissions and approvals. The assistance was given starting from regulatory advice during product development, controlled correspondence with FDA, writing of scientific dossier in CTD, conversion into eCTD, online submission support to USFDA, query response and product approval.

UMBRELLA OF SERVICES UNDER EUROPE ECONOMIC AREA

ASMF (EU-MSs), CEP(EDQM)

EU-MSs — ASMF

- For Pharmacopoeia and non-pharmacopoeia API
- Writing Applicant part (AP) and Restricted Part (RP) of ASMF
- Submission to each MSs
- Query response
- ASMF acceptance

EDQM — CEP

- For Pharmacopoeia API
- Writing Applicant Part (AP) and Restricted Part (RP)
- EDQM submission
- Query response
- Support for EDQM site inspection
- CEP approval letter

API EU QP AUDIT

A	B	C	D
THIRD PARTY API QP AUDIT	AUDIT REPORT	CAPA PREPARATION	CAPA ACCEPTANCE BY EU QP AUDITOR
EXPERIENCED EU QP AUDITOR	3 YEARS VALID	SUBMISSION TO SINGLE EU QP	QP DECLARATION

INFORMAL MILEAGE

- One- time audit by an independent auditor for single API
- Conserves company's resources (i.e. cost of travel and stay for buyer specific auditor, one-time engagement of manufacturing and QA personnel)
- One single QP audit can replace numerous MA holder audits
- Single comprehensive CAPA execution to independent EU QP auditor as against multiple CAPAs to different EU QP auditors
- Reduced major observations during renewal inspections since EU QP audit by ex-agency inspector

MAH & MEDICINES IMPORT IN EU

- Local legal establishment in EU to:
  - Hold Marketing Authorisation for Drugs
  - Perform EU QP audit
  - SME status to avail regulatory fees reduction
- Local liasoning firm with regulatory authorities for DCP procedures.
- Tie up with local wholesale distributors and importers for QP Batch Release and import agreements.

EU MAA SUBMISSION AND APPROVAL

EU LEVEL ASSISTANCE

- DCP slot booking
- MA holder based out of EU
- EU QP Audit
- EU Batch Release Site identification (BRS)
- PIL & bridging study
- EU QP PV

MAA SUBMISSION

- m1 package
- m2- 2.3, 2.4, 2.5, 2.6 and 2.7 scientific writing
- m3- CMC data review and module 3 script
- m4 and m5- based on scientific articles
- Article 10(1)- Generic, Article 10(3)- Hybrid, Article 10(a) – well established use, Article 10(b)- fixed combination application

PRODUCT LICENSE AND MARKET APPROVAL

- Electronic submission to RMS and CMSs
- RMS Query response (D100)
- Receipt of Product LIcense
- Submission in each CMSs for MAA and pricing approval

EXPERTISE OF EMERGING MARKETS

COMPETENCE & PERFORMANCE WITH EMERGING AGENCIES

ASEANs

- More than 500 products approval in basket
- Managed various dosage forms in different therapeutic areas

SAGA

- Anti-malarial and anti-retroviral dossiers submission
- National application writing, submission, query response and approval for most of the African markets
- Liasoned with North, East, Central, West and South African agencies

BRICS-TM

- 5-10 dossiers submission per year in Brazil, Russia, South Africa, Mexico
- Successfully managed ANVISA submission, local PE, CT, Dissolution and analytical validation
- Phase I CTA application with DCGI India
- Fast track application with SAHPRA for first generic

GCC

- Centralised Application for Oral solids and Topicals
- GCC GMP inspection management
- National application in each of GCC markets successfully managed

RoW

- First ever cytotoxic injectables approval in Kazakhstan
- More than 1000 approvals in Rest of World markets in different therapeutic areas

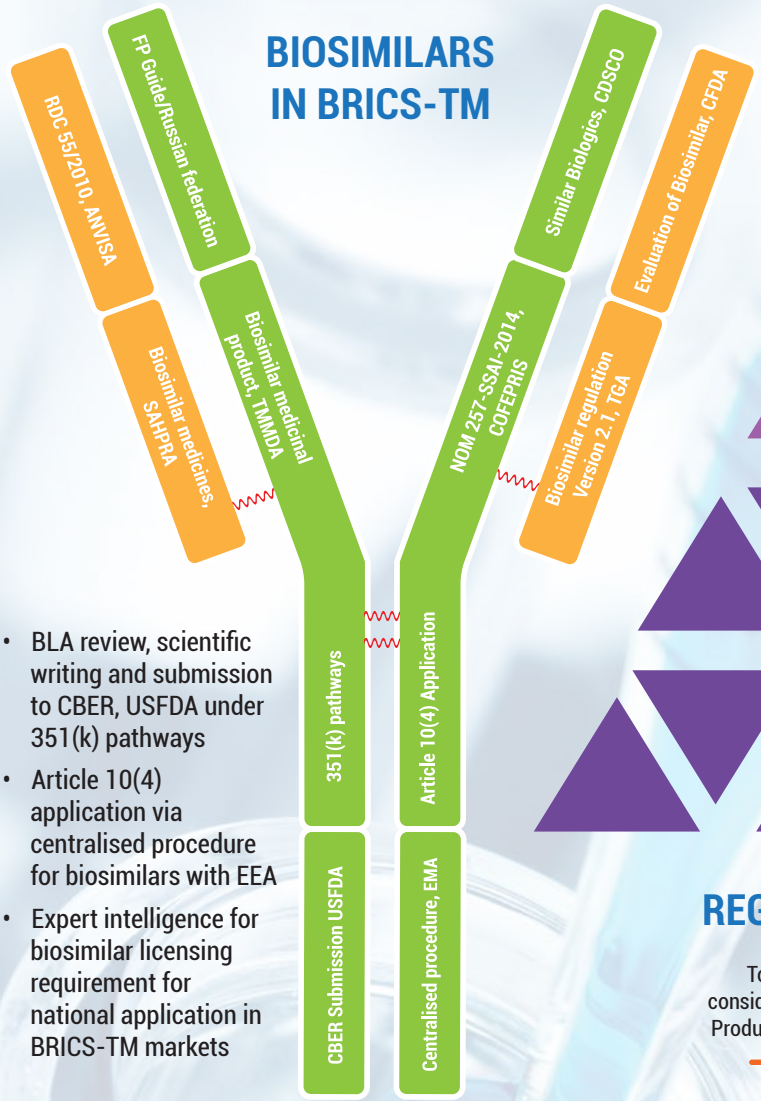
WHO PQP -SPEEDY ACCESS IN 35 EMERGING ECONOMIES

WHO PQP EOI → INSPECTION → DOSSIER EVALUATION → WHOPAR → COLLABORATIVE PROCEDURE → 35 MARKETS ACCESS

Approach us for speedy access to 35 emerging markets!!			
Armenia	Botswana	Burkina Faso	Burundi
Cameroon	Cote'd Ivory	Congo	Eritrea
Ethiopia	Georgia	Ghana	Jamaica
Kenya	Kyrgyzstan	Republic of Laos	Madagascar
Malawi	Mali	Mozambique	Namibia
Nigeria	Pakistan	Philippines	Senegal
Sierra Leone	South Africa	Sri Lanka	Ukraine
Thailand	Trinidad & Tobago	Uganda	Zambia
Tanzania & Zanzibar	Zimbabwe		

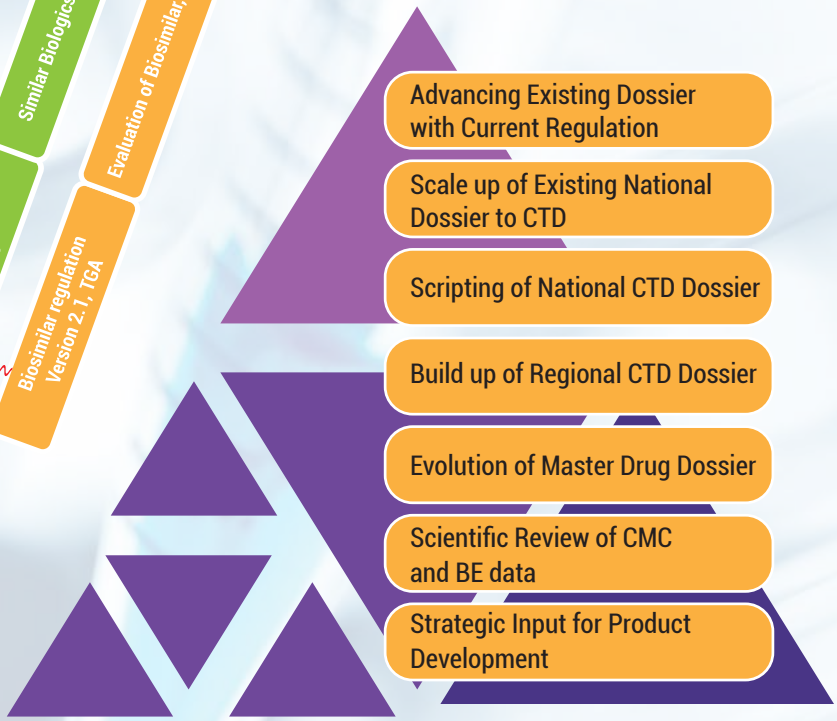
REGULATORY INTELLIGENCE

BIOSIMILARS IN BRICS-TM

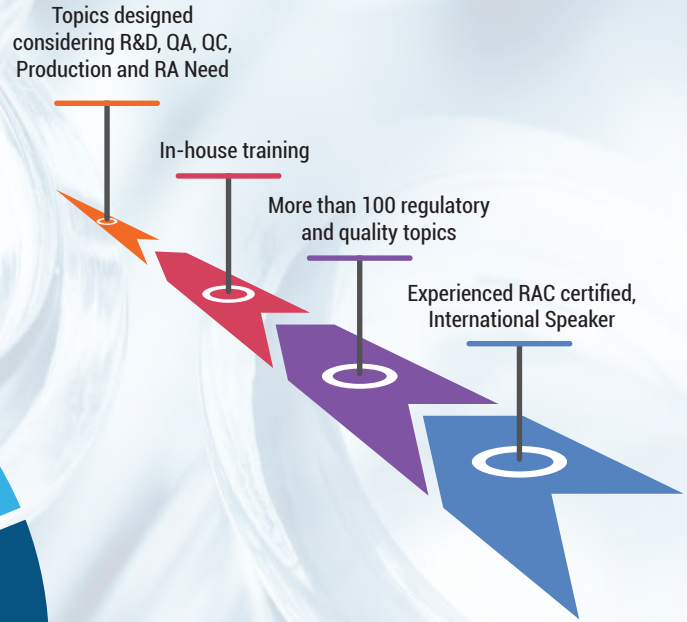


- BLA review, scientific writing and submission to CBER, USFDA under 351(k) pathways
- Article 10(4) application via centralised procedure for biosimilars with EEA
- Expert intelligence for biosimilar licensing requirement for national application in BRICS-TM markets

GLOBAL DOSSIER DEVELOPMENT



REGULATORY INSIGHT & GUIDANCE



- Master checklist for Asia, Africa, Russia/CIS and Latin American countries based on current and valid guidelines covering agencies experience of approvals
- Ongoing regulatory training conducted to pharmaceutical companies

PRODUCT LIFECYCLE MANAGEMENT

GxP EXCELLENCE

GxP INSPECTIONS

- ARD & F&D Site GMP verification
- API & FDF Mfg Site GMP verification
- BE & Clinical Site GCP verification
- GLP verification Audit

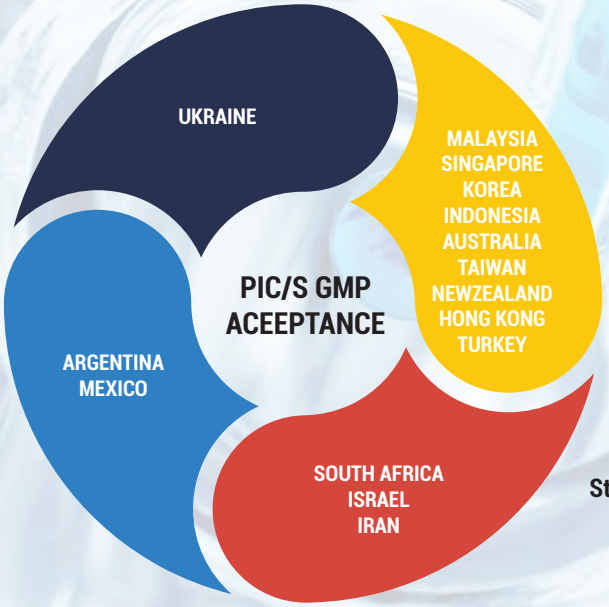
EU GMP (HUMAN & VET MEDICINES) & PIC/S GMP PERSUITS

GAP ANALYSIS AUDIT
- Gap analysis audit & report
- Regular visits to verify facility, utility, laboratory, personnel and quality system
- System upgradation advice
- GMP Inspection application

INSPECTION
- Scheduling GMP inspection
- Support throughout Inspection
- CAPA and support till approval

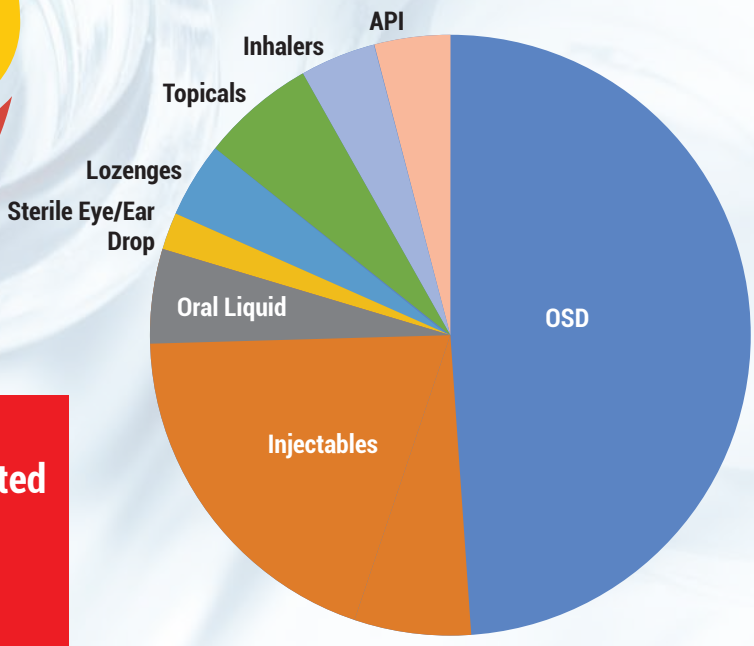
EU GMP ACCREDITATION
- Securing EU GMP certification
- Updates on EudraGMP portal
- Annual report submission
- Renewals insepction support

PIC/S GMP INSPECTION & ACKNOWLEDGEMENT IN EMERGING MARKETS



INCREDIBLE EU GMP SUCCESS

- The GMP service of Metina is considered as paramount triumph.



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