



**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

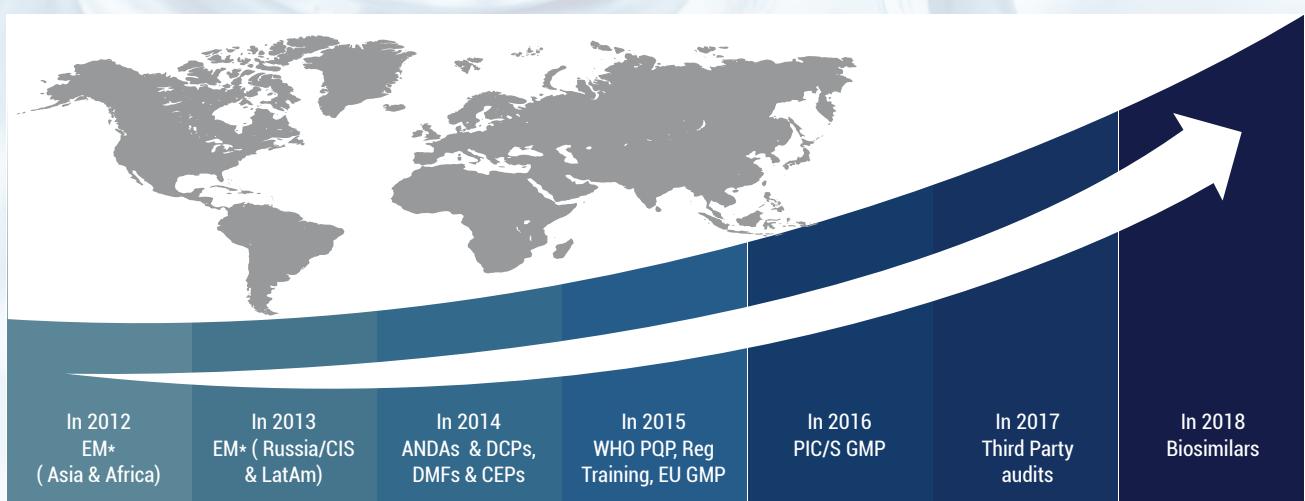
Corporate Profile

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	hasumati@metinapharmconsulting.com	Membership	Regulatory Affairs Professional Society (RAPS), The Organization for Professionals in Regulatory Affairs (TOPRA)
Founder & Director	Mrs. Hasumati Rahalkar		
Business	Comprehensive consultancy services in GMP and Regulatory Field	Presence	Global

GLIMPSE OF METINA



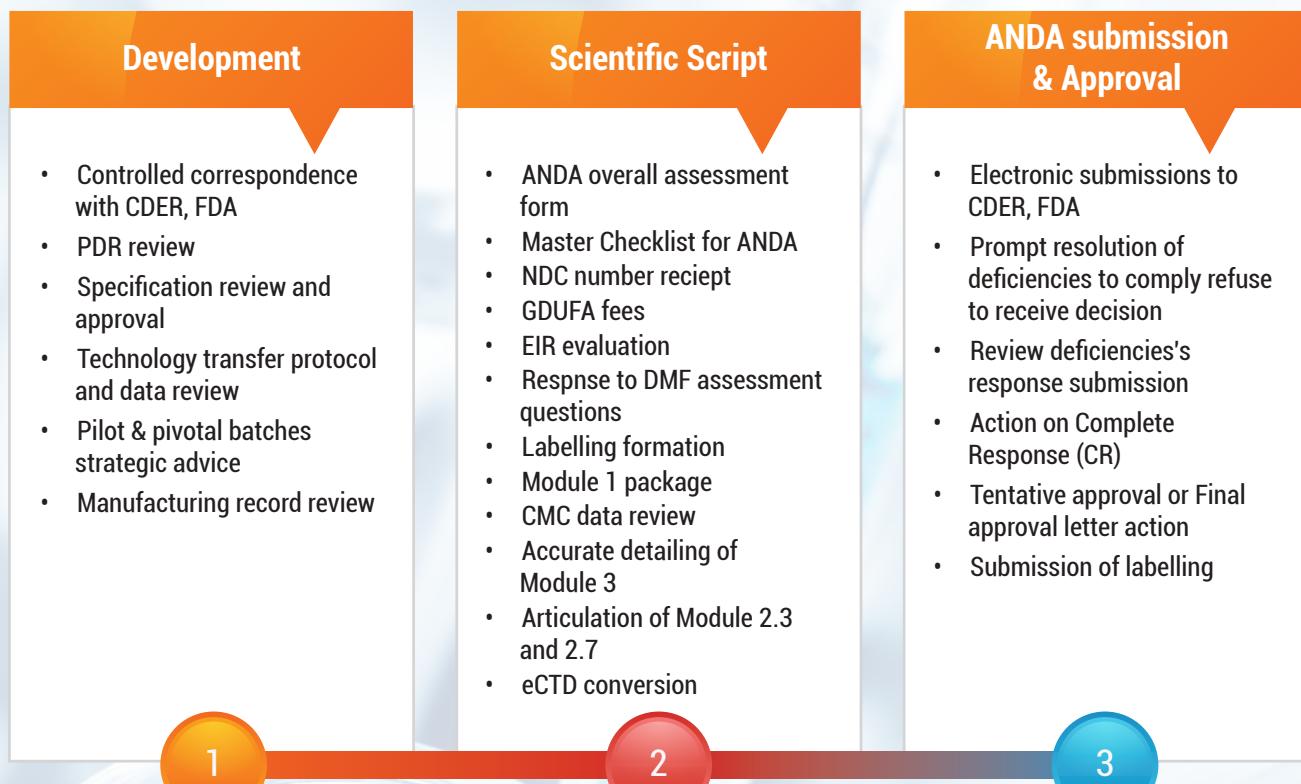
BUSINESS GROWTH INDEX



*Emerging Market

ANDA SUBMISSIONS AND APPROVALS

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



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

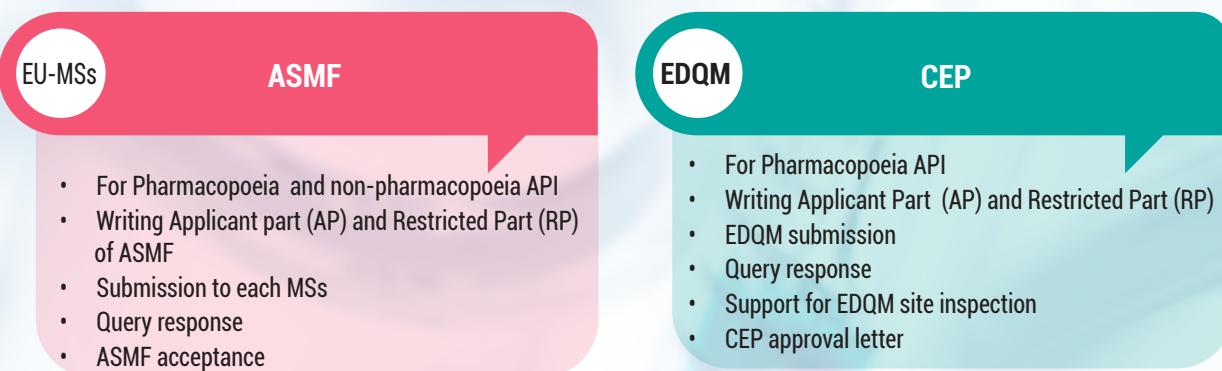
AT HAND LICENSED ANDAs



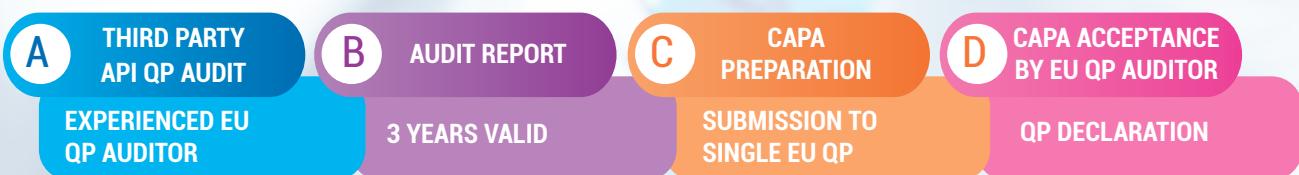
Metina has efficiently managed multiple ANDAs submissions and approvals. The assistance was given starting from regulatory advice during product development, controlled correspondence with FDA, writing of scientific dossier in CTD, conversion into eCTD, online submission support to USFDA, query response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

UMBRELLA OF SERVICES UNDER EUROPE ECONOMIC AREA

ASMF (EU-MSs), CEP(EDQM)



API EU QP AUDIT



INFORMAL MILEAGE

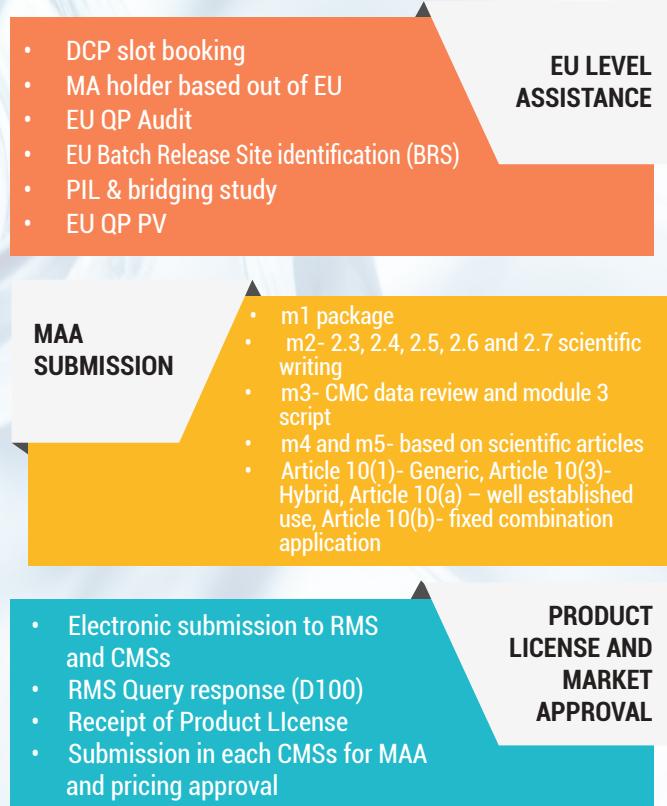
- One- time audit by an independent auditor for single API
- Conserves company's resources (i.e. cost of travel and stay for buyer specific auditor, one-time engagement of manufacturing and QA personnel)
- One single QP audit can replace numerous MA holder audits

- 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

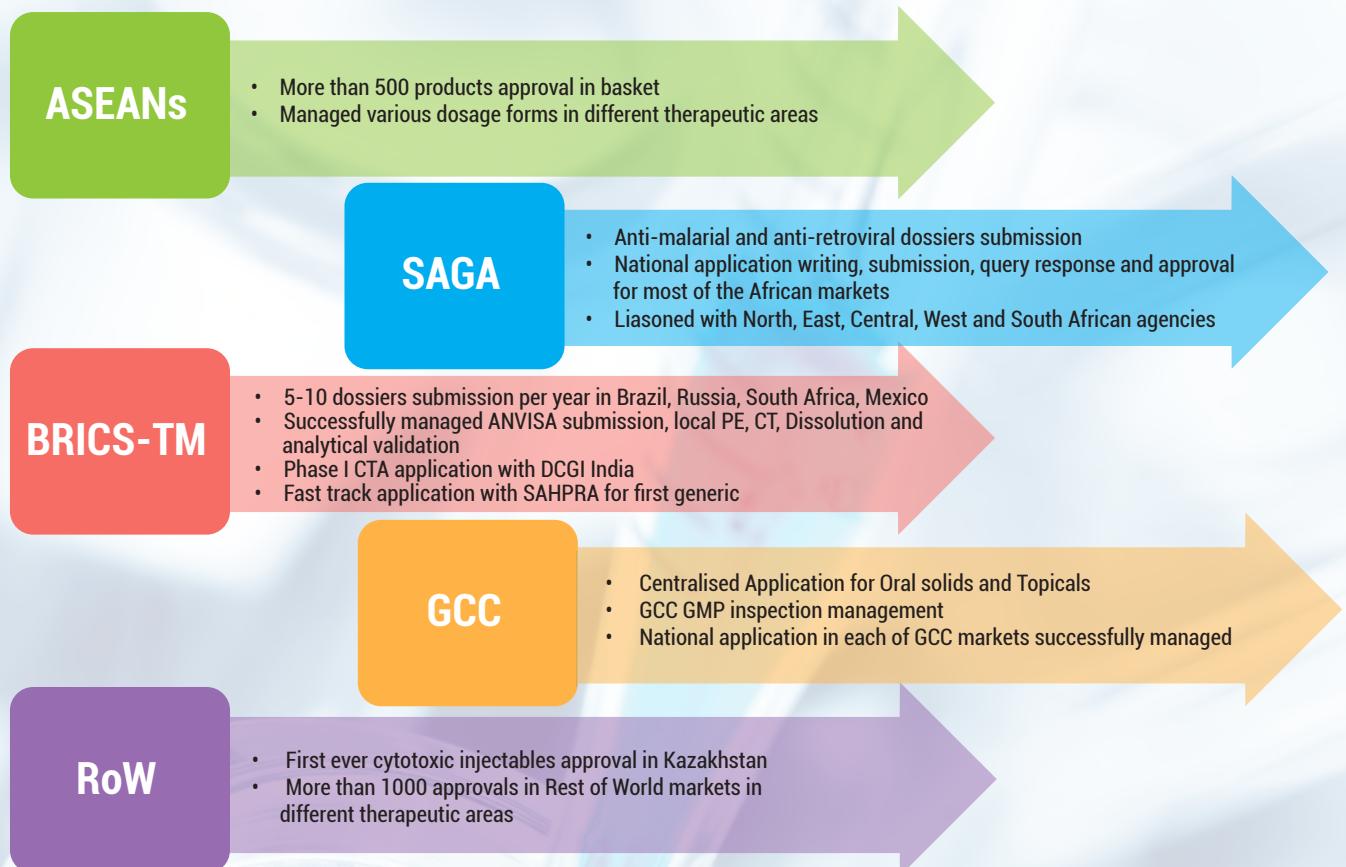
- Local legal establishment in EU to:
 - Hold Marketing Authorisation for Drugs
 - Perform EU QP audit
 - SME status to avail regulatory fees reduction
- Local liaisoning firm with regulatory authorities for DCP procedures.
- Tie up with local wholesale distributors and importers for QP Batch Release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

EU MAA SUBMISSION AND APPROVAL

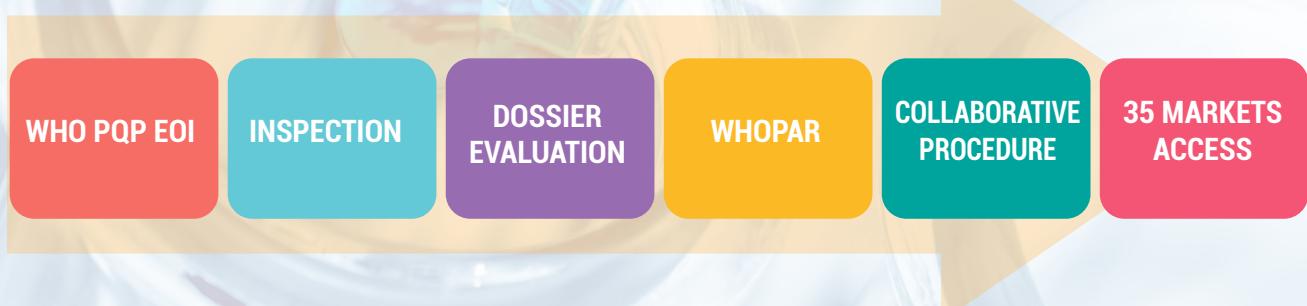


EXPERTISE OF EMERGING MARKETS

COMPETENCE & PERFORMANCE WITH EMERGING AGENCIES



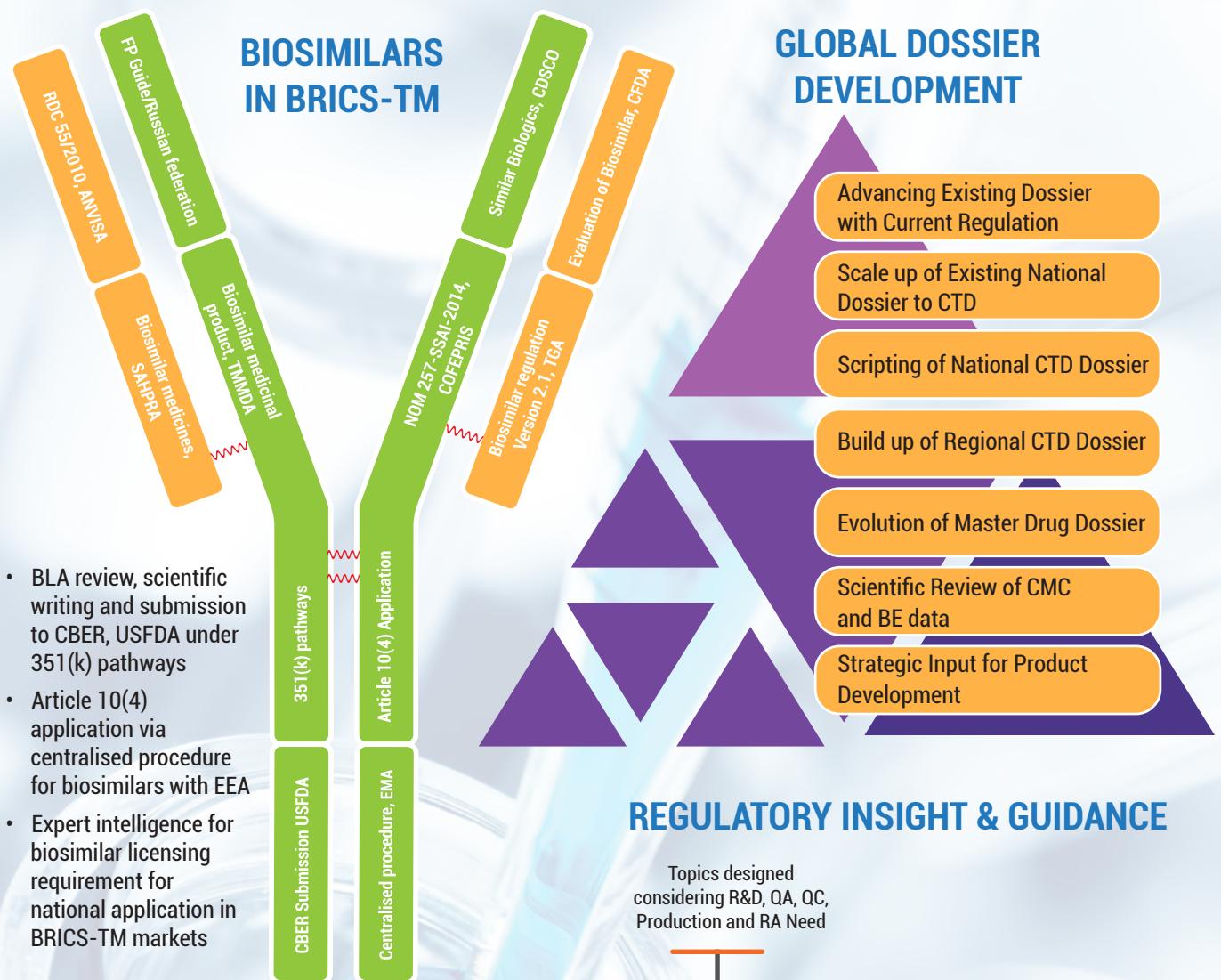
WHO PQP -SPEEDY ACCESS IN 35 EMERGING ECONOMIES



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



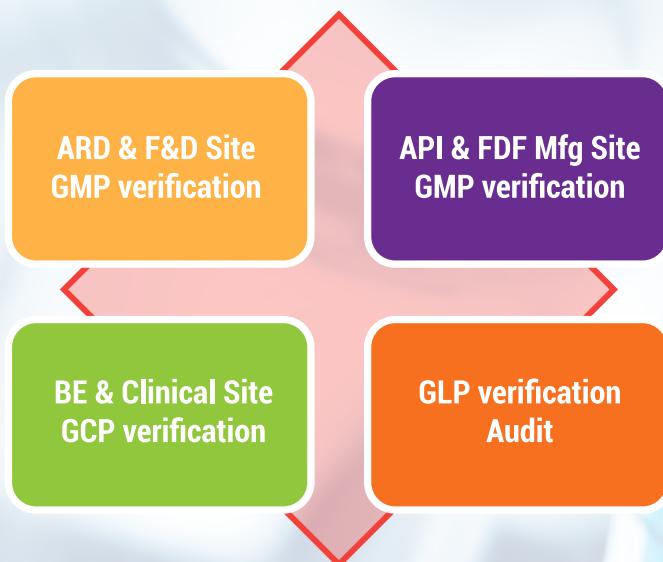
PRODUCT LIFECYCLE MANAGEMENT



- 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

GxP EXCELLENCE

GxP INSPECTIONS



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

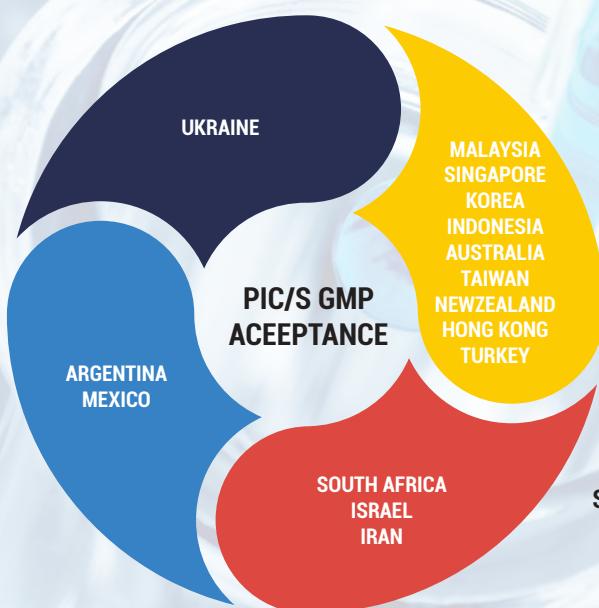
INSPECTION

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

EU GMP ACCREDITATION

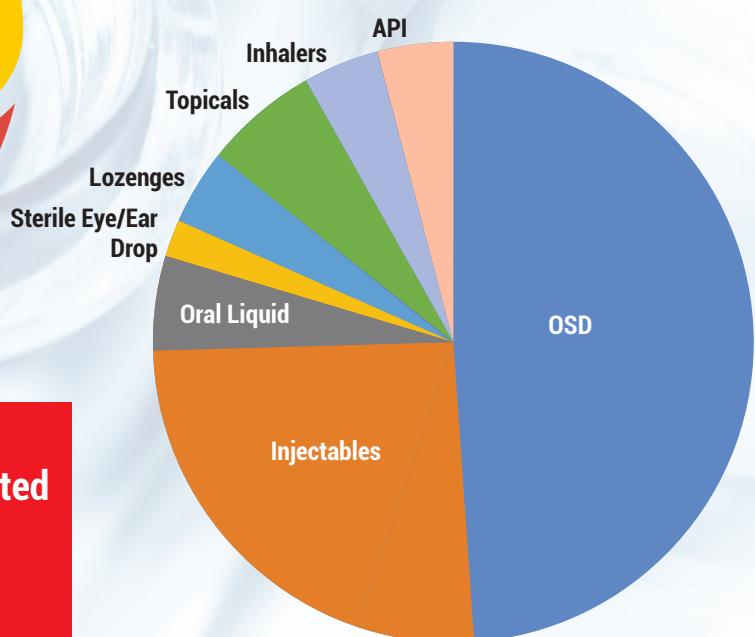
- Securing EU GMP certification
- Updates on EudraGMP portal
- Annual report submission
- Renewals inspection support

PIC/S GMP INSPECTION & ACKNOWLEDGEMENT IN EMERGING MARKETS



INCREDIBLE EU GMP SUCCESS

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



Contact us :

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