



**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

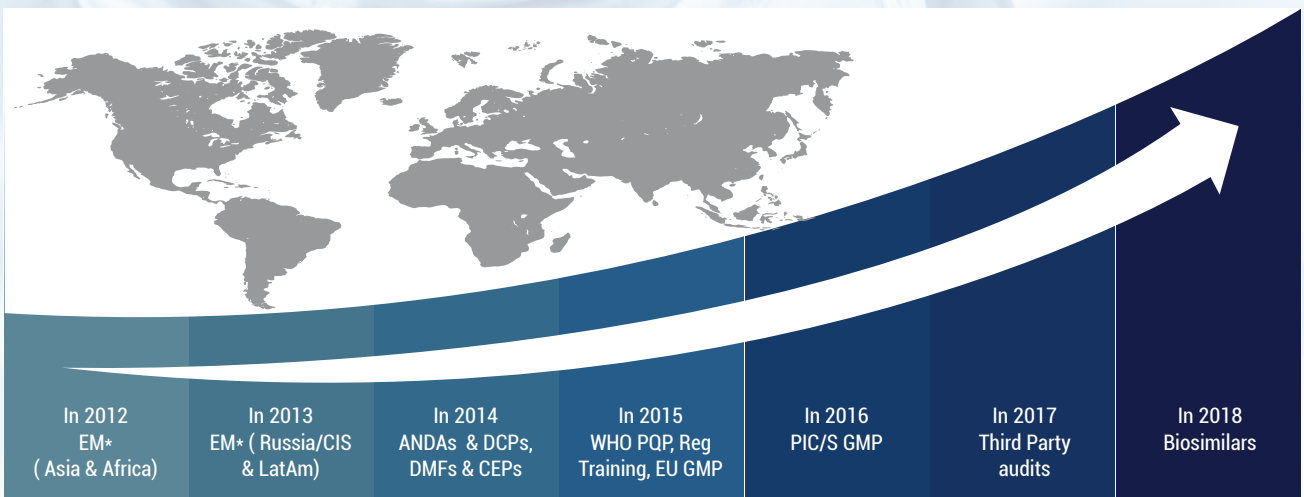
## Corporate Profile

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

# GLIMPSE OF METINA



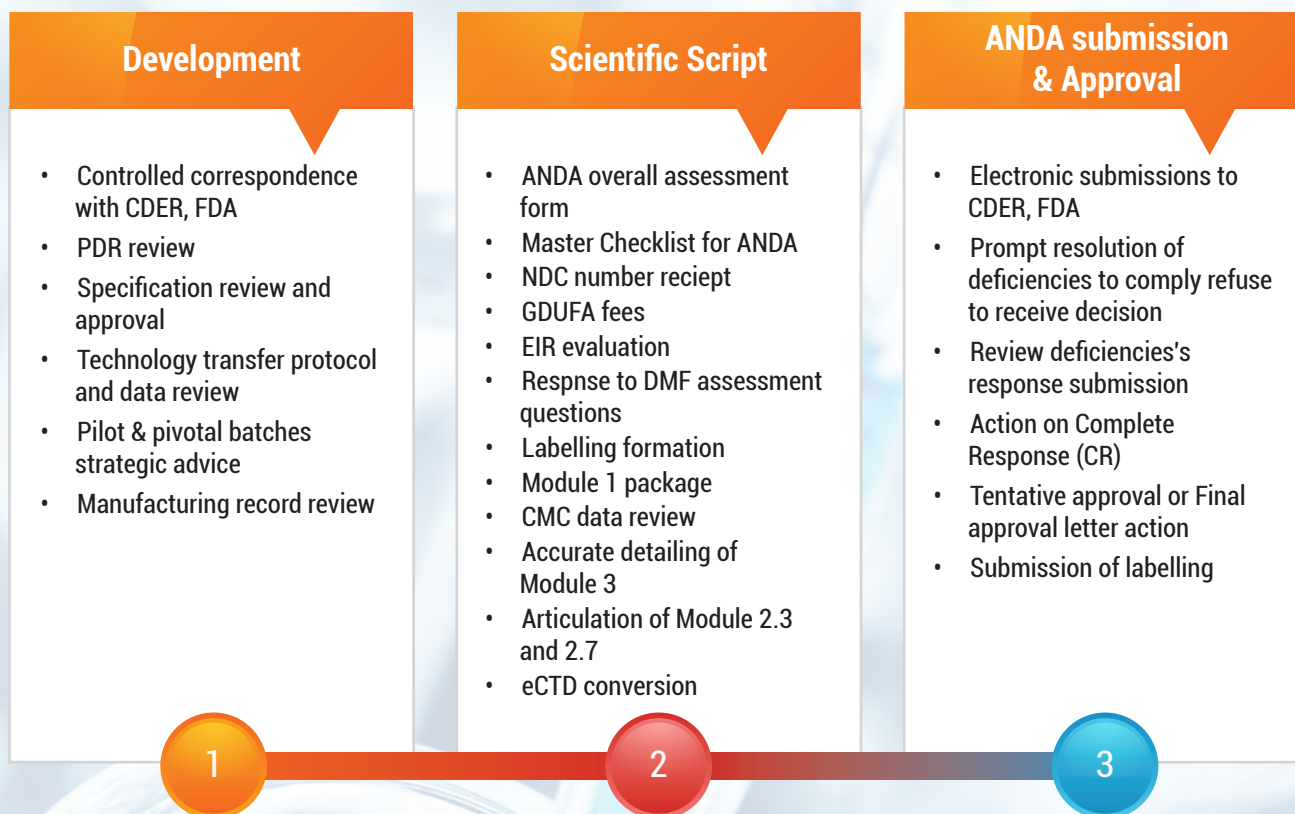
## BUSINESS GROWTH INDEX



\*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)

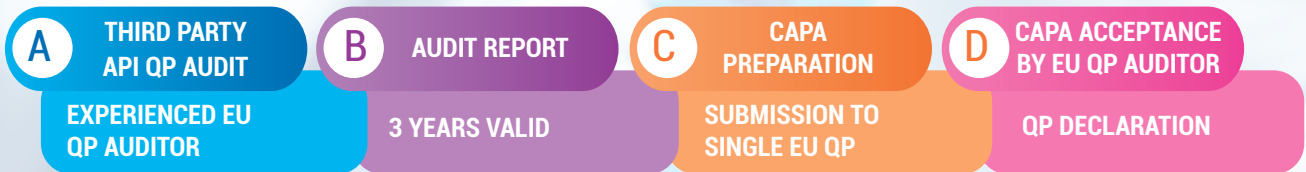
**EU-MSs** **ASMF**

- 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



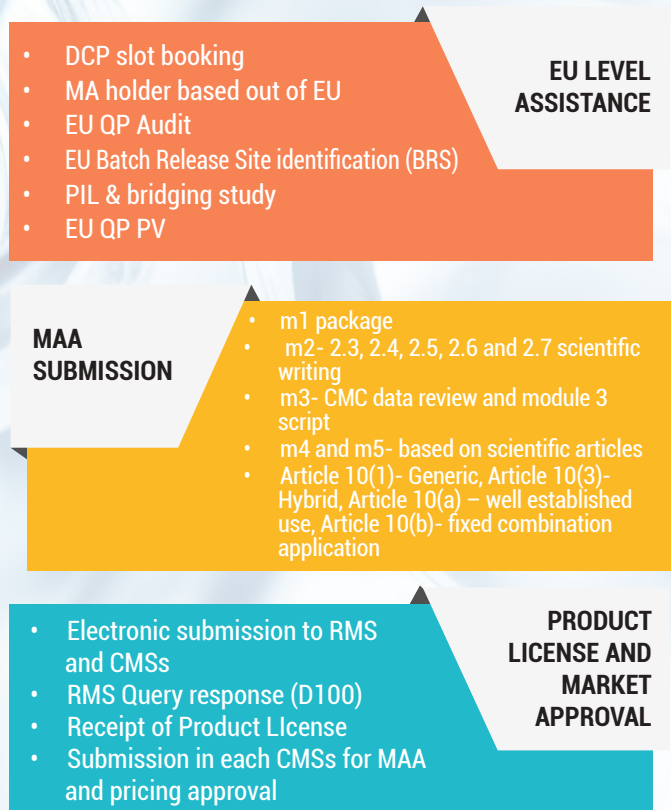
### INFORMAL MILEAGE

- 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

## EU MAA SUBMISSION AND APPROVAL

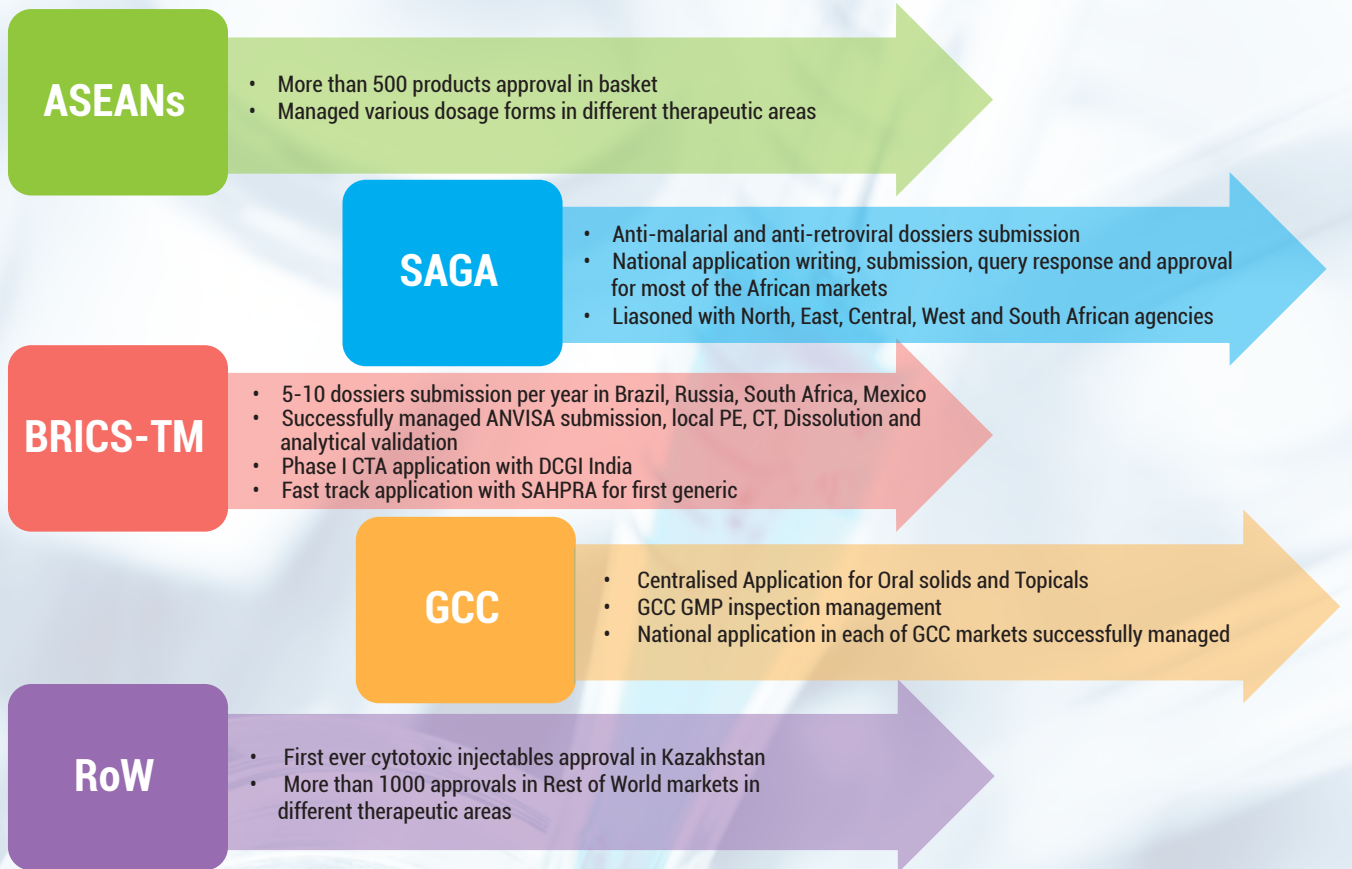
### MAH & MEDICINES IMPORT IN EU

- 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.

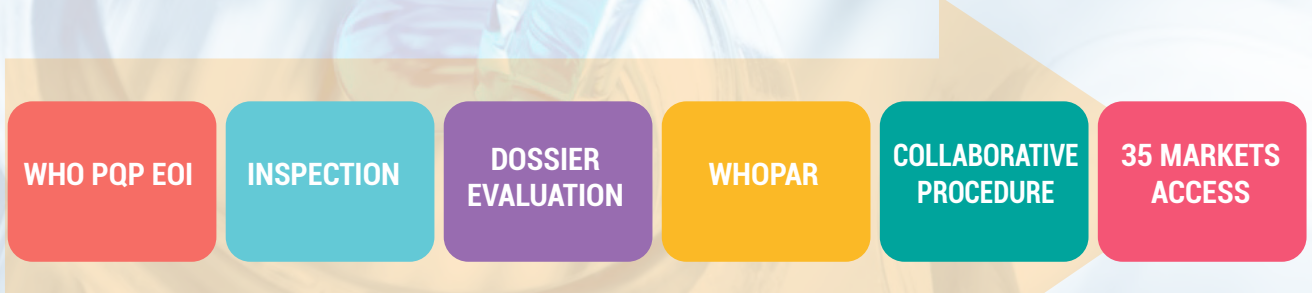


# EXPERTISE OF EMERGING MARKETS

## COMPETENCE & PERFORMANCE WITH EMERGING AGENCIES



## WHO PQP - SPEEDY ACCESS IN 35 EMERGING ECONOMIES

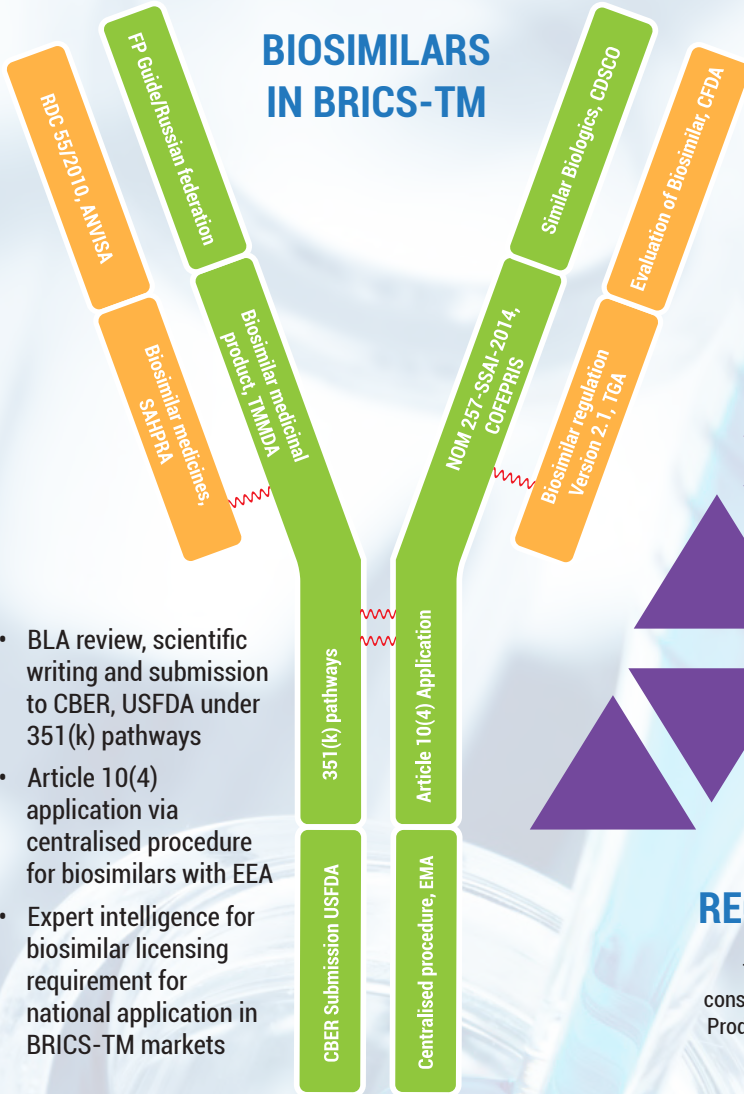


**Approach us for speedy access to 35 emerging markets!!**

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		

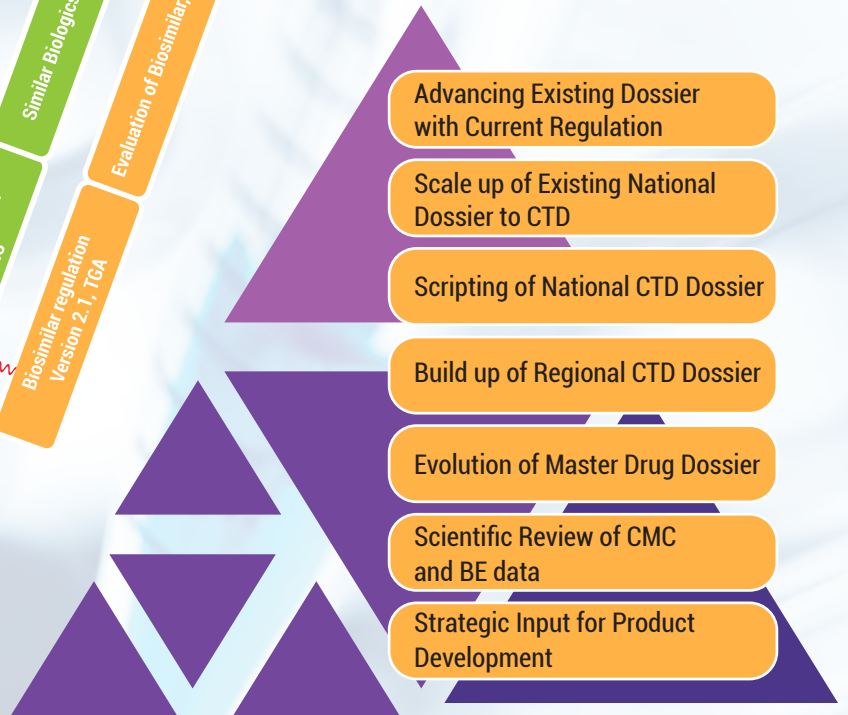
# REGULATORY INTELLIGENCE

## 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

Topics designed considering R&D, QA, QC, Production and RA Need



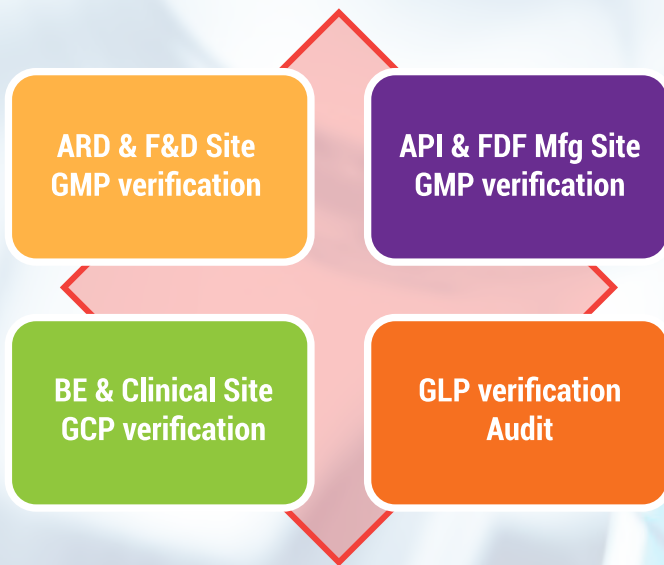
## PRODUCT LIFECYCLE MANAGEMENT



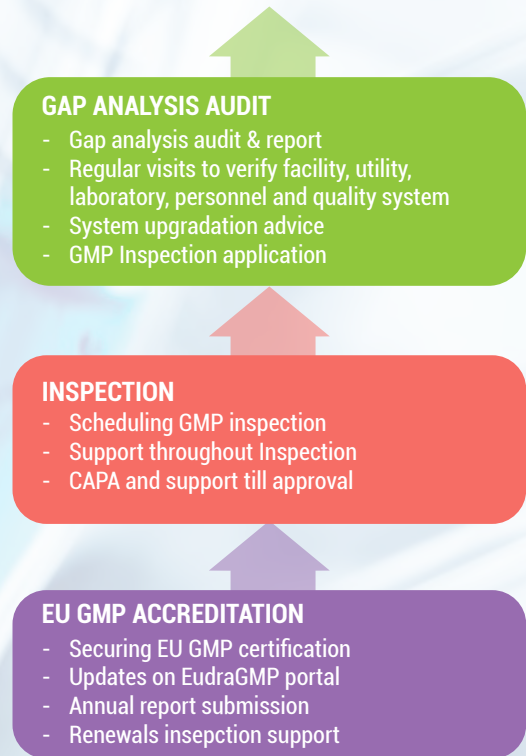
- Master checklist for Asia, Africa, Russia/CIS and Latin American countries based on current and valid guidelines covering agencies experience of approvals
- Ongoing regulatory training conducted to pharmaceutical companies

# GxP EXCELLENCE

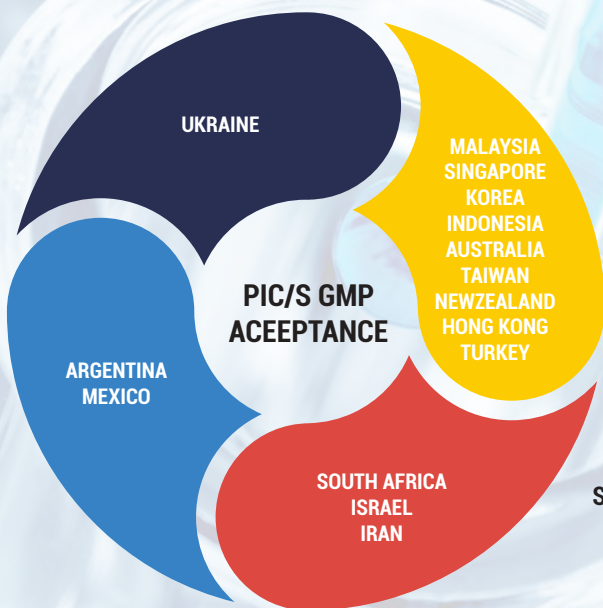
## GxP INSPECTIONS



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

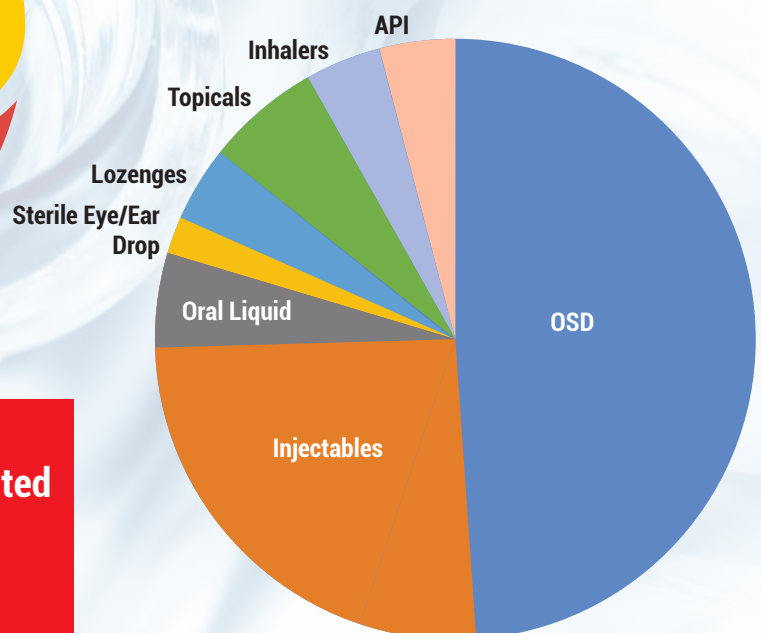


## PIC/S GMP INSPECTION & ACKNOWLEDGEMENT IN EMERGING MARKETS



## INCREDIBLE EU GMP SUCCESS

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



Contact us :

**Metina Pharmconsulting Private Limited**

901 -903, Goodwill Infinity, Sector 12, Kharghar,  
Navi Mumbai- 410210

Maharashtra, India

Tel: + 91 22 6243 3000

Email ID: [info@metinapharmconsulting.com](mailto:info@metinapharmconsulting.com)

Website: [www.metinapharmconsulting.com](http://www.metinapharmconsulting.com)