PHARMEXPERT

Pharmexpert Consultant LLP

GXP & Regulatory Services

About Us

PHARMEXPERT

2017

- GMP Compliance Upgradation
- Commissioning Qualification
- QMS Set up

2018

- First USFDA certificate at Client's site
- Supplier Qualification GMP Audits
- Regulatory Support

2019

- Independent GMP Audit
- Audit Report Library
- GCP monitoring, R&D support

2020

- Considered as most trusted GMP and Regulatory service provider

VISION

To support Pharmaceutical industries globally and be sustainable by providing the solutions that meet the highest levels of quality standards in an efficient manner

MISSION

To be the leading and most trusted GxP service provider globally while maintaining the highest level of integrity.

Service Portfolio

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GMP

- **Audits**
- **Audit Report Database**
- **Quality Compliance & Upgradation**
- Quality Engineering
- GMP Consulting

REGULATORY AFFAIRS

- DMF/ Dossiers (CTD/e-CTD Compilations)
- **Pre & Post Submissions**
- Technical Packages
- Life cycle management
- Procedure Management
- Medical Writing

CLINICAL RESEARCH – GCP

- **Audits & Monitoring** (BA/BE-Phase 1 and Phase Trials, Bioanalytical & others)
- **Project Management**
- Consulting- CRO set up & Up gradation
- PK stat review

PHARMEXPERT CONSULTING

- **Sourcing of API & FDF**
- Contract Manufacturing
- **Training**
- Research & Development (R&D) Support
- Pharmacovigilance Support
- Business Support
- Project management
- **Temporary Staffing**

GMP Services- Overview

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Audits

- **Supplier Audits**
- Pre-inspection Audits
- **Combination Audit**
- QMS / GAP / Root Cause
- Due – Diligence Audit
- Independent Audit (Sponsored / Partnership)
- **AUDIT REPORT DATABASE**

Quality Compliance

- **USFDA/EU/ WHO/PIC/s GMP Certification**
- Quality System Design/Development/ Implementation
- Post Inspection /Remediation (483s / Warning Letters)

Quality Engineering

- Conceptual, Basic & Detailed Engineering
- Commissioning & Qualification (C&Q)
- Validation
- Procurement Support
- Project Management & Construction Supervision

GMP Consulting

- **Pharma Plant Set-Up**
- QP Services
- Computerized System Validation (CSV)
- Training
- Monitoring
- Contract Manufacturing

Our Auditors / Consultants Global Presence:

GMP- Quality Compliance & Upgradation

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An Integrated solution for establishing & upgrading GMP Compliance at time-effective manner

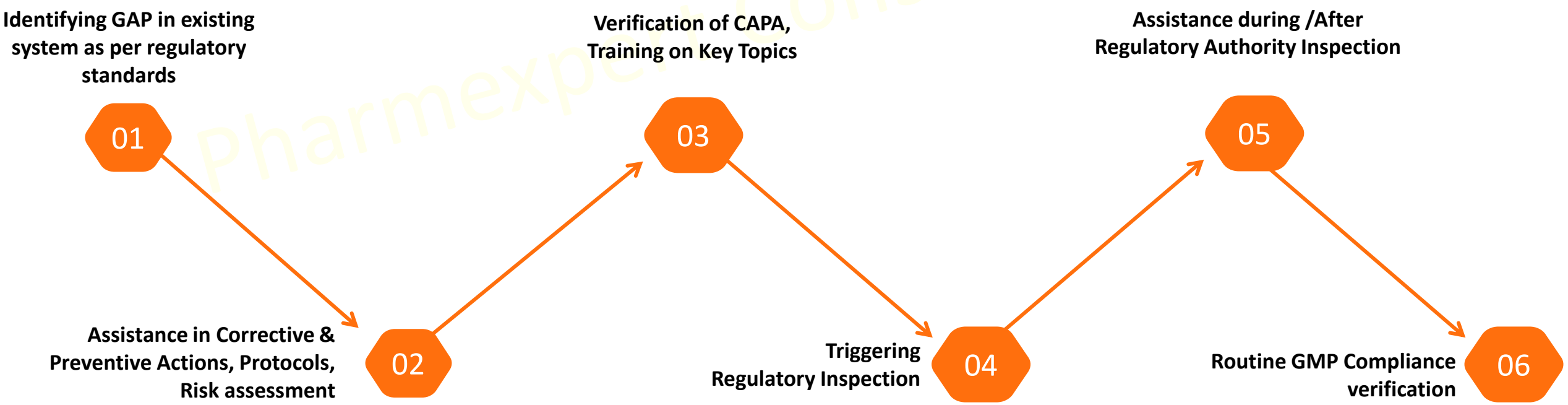
U.S. FOOD & DRUG ADMINISTRATION

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PIC/S

World Health Organization

ANVISA



GMP Services – Engineering

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Conceptual Engineering

Identify technical & economic feasibility of Plant Set – Up project by conducting a preliminary study (feasibility study) w.r.t to GMP guidelines.

Basic Engineering

Provide design details including field studies, especially of a topographical, geological, geotechnical, hydrological and hydraulic nature

Detailed Engineering

Provide construction details by discipline (Civil, Mechanical, Process, Electric, Telecommunications, Instrumentation & Control, Computer Systems)

Validation

We serve all Validation project requirements from URS, FRS, DQ, FAT, SAT, Commissioning documents, VMP, IQ, OQ, PQ, PV to Validation Report writing.

Procurement

Procurement of all types of Equipment's, Utilities, Clean Room Panels etc. as per URS / BOQ / Tender Documents

Commissioning & Qualification (C&Q)

GMP-compliant for all Equipment, Utilities & Facilities as well as Validation to ensure reproducibility of Processes for Production, Cleaning, Analytic Methods & Computer Systems.

PROJECT MANAGEMENT & Construction Supervision

Regulatory Affairs- Overview

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During Life cycle

- Regulatory Intelligence services and decoding dossier requirements
- Pre submission assessment and compilation
- Registration and application of NDA, ANDA, IMP and Biosimilar
- Relaunch of product in new market

Pre-Submission

- Registration and self-identification i.e. D-U-N-S number, FEI number request
- Compilation and Investigational New Drug - IND Application
- Compilation and NDA and ANDA
- Compilation and Investigational Medicinal Product Dossier (IMPD)
- Marketing Authorization Application (MAA) to Europe via appropriate procedure
- MAAs for Biosimilar product
- Certification of suitability for EU
- Dossiers for emerging countries (RoW market)

During Submission

- Expert help in addressing Regulatory queries and concern like RTR, Further information request
- Control correspondence with Regulatory agency
- Preparation of response/Justification/clarification documents for regulatory queries are.

Post-Submission

- Post approval updates
- Renewal of Dossier
- Annual Report for post MAA
- Registered Dossier Extension to other regulated or emerging markets
- Dossier preparation to resubmission
- Review of Rejection of Application and designing justification report

GMP Services – Consulting

PHARMA PLANT SET-UP :

Extensive experience for **complete setup of pharmaceutical manufacturing unit** which includes IV fluids, Injectable, Tablet, Capsule, Liquid orals / externals, Powders, Bulk drugs, Ointment / Cream manufacturing plants.
Handling of **Green /Brown Field Projects**.

TRAINING :

Training on **all GXP topics , Data Integrity and Customized topics.** Help to enhance operational excellence and serve as best tool to mitigate risks

QP SERVICES :

Product Release
API / Formulation QP Audits & Certification
Documents Evaluation
Permanent / Short Term QP Cover
Quality System Review
Risk Management

REGULATORY AFFAIRS :

Provide **CTD/eCTD Dossier Compilation & Submission, User Testing & Medical Writing** services.
Pre & Post Submission Services

Pharmexpert Consulting

SOURCING :

Procurement of **best quality of Raw Materials, Packing Materials & Finished Goods at competitive price** from established manufacturers /trading houses across the globe

MONITORING :

In-process monitoring of manufacturing operations: Include Dispensing to Packaging of the final product

BUSINESS SUPPORT :

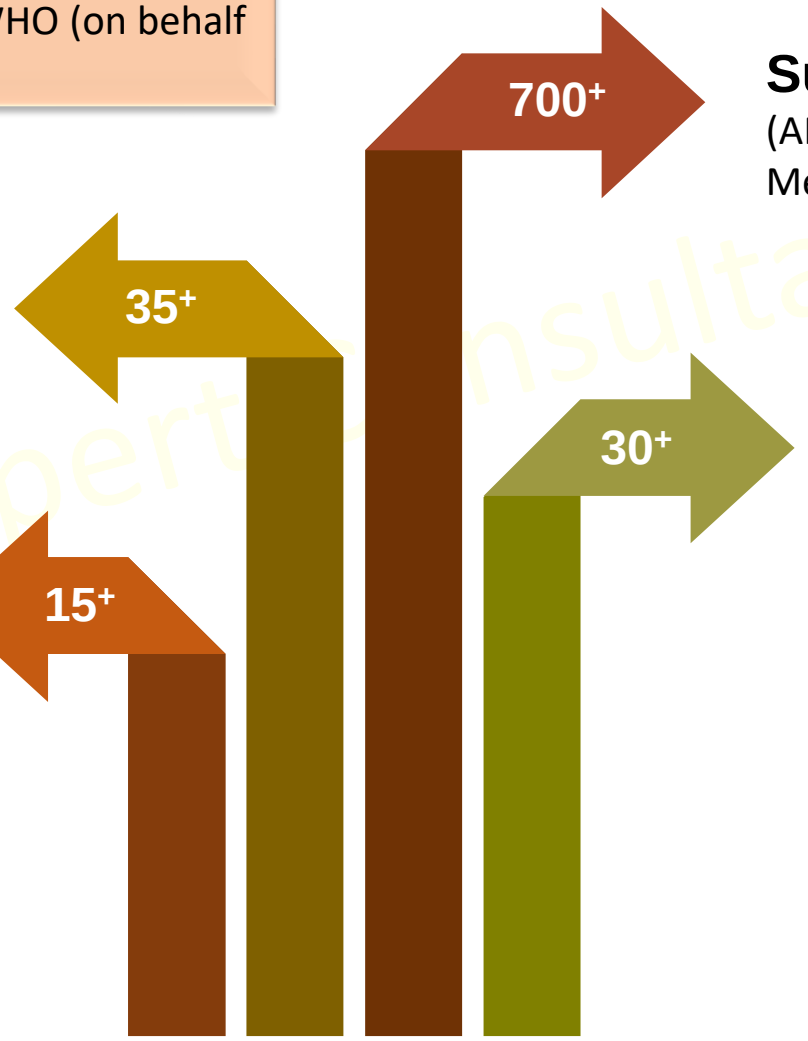
Assisting Clients **strategically position & promote** products & services into new markets, attract new customers, increase sales & **ultimately increase profit.**

CONTRACT MANUFACTURING :

Help to find best quality CMOs worldwide. With a guarantee of GMP Compliance & Pharmexpert Reliability.

Our Experience

- Regulatory Inspection faced: USFDA, EMS, WHO, PICS, ANVISA, COFEPRIS
- Audit Report submitted to USFDA, EMA, PICs, WHO (on behalf of our clients



Supplier Qualification Audits
(API, KSM, Intermediates, Excipient, PM, Medical device mfg., CMO, Lab etc.)

Commissioning & Validation Projects

Pharma Plant Set – Up Projects

GMP Compliance & Upgradation Projects

40+ **Independent GMP Qualification Audits**

Consulting & Sourcing Satisfied Clients **60+**

Clients Served/Inspected: Global

PHARMEXPERT

Amarox UK

Farmigea

CFM

Cerbios

IBSA

Ethypharm,

AET

Selectchemeie

GAP

Chanelle

Vinus

Venifar

GM Pharma

Medipharm

BIQLJ China

Aspar

One Pharma

Natrix science

Lonza – Capsugel Belgium

Gerresheimer Glass INC USA

Procos Spa Italy

Acarpia

Zhejiang Huida Biotech

Shanghai Haoyuan Chemexpress

Dongkook , Korea

Shandong Zouping Dazhan

Zhejiang East, China

Joyang lab,china

Hikang, China

Portan China

Beijing Hope China

Hisun Pharma

Fujian south Nantong

Shandong weifang

Shandong Jinghua

Zhejiang Xianju

Clients Served / Inspected : India

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Hetero Labs Limited (All sites)
Hetero Drugs Limited (All sites)
Symed (All sites)
Honour (All sites)
Medreich (all sites)
Sun Pharma
Symbiotec
Morepen
INDSWIFT
Cipla Ltd.
Lupin Ltd
Zydus Healthcare
Cadila Pharma
Aurobindo Pharma

Schott
Vasudha Pharma
Hikal Ltd.
MSN Labs
MSN Pharmachem
Indoco Remedies Limited
Kreative Organics Private
Neuland Laboratories Limited
Wanbury Limited
IOL
Farmenta
Chromo Laboratories
Srikem Laboratories Pvt. Ltd.
VKT Pharma

Aspiro
Medinex
Amoli Vapi, Amoli Baroda
Spensules
Kopran
Nakoda
Torrent Pharma
Intas Pharma
Medicef Pharma
Shreeji Polymer Chemworth
Indorama Engineers
Dr. Reddys Limited
Aurore Pharma
Milan Lab
Many more into list……..

Executed Greenfield and Upgradation Projects:

- NIRA LIFE SCIENCE PVT LTD
- NABROS
- APISYN HEALTHCARE
- KWALITY PHARMA
- RUSAN PHARMA
- GN PAL
- MAXMED PHARMA
- DAMAIRA
- VALENCE PHARMACHEM
- DOSHION PHARMA
- INDORAMA
- ALLIED
- PHARMASYNTH
- AVEO
- BEACON
- SERUM INSTITUTE OF INDIA LTD.
- BIODEAL
- LEWENCE PHARMA
- AKSHARAMA PHARMA
- CAPS NUTRA
- SHAPE PHARMA
- CADILA HEALTHCARE LTD. [ZYDUS GROUP]
- DISHMAN PHARMACEUTICALS & CHEMICALS LTD.
- NIRMA HEALTHCAE LTD.
- ZYDUS HEALTHCARE & RESEARCH PVT LTD.
- LABORATE
- TASMED

Many more in list……

Our Key GXP Team

Vipin Sharma– Master degree in Pharmacy Having 17 years Experience in Quality Assurance in Pharmaceutical Formulation Companies. He has independently faced more than 30 regulatory audits such as USFDA, MHRA, TGA, EUGMP, NDA, PPB, TFDA and many more.

Priyanka Siddhpura – Master degree in Pharmacy Having 13+ years Experience in Quality Assurance in Pharmaceutical Formulation and API Companies. She has performed more than 200 GMP audits of API facilities globally & has also helped many companies to clear their USFDA, MHRA, TGA, EU GMP, WHO-GMP etc.

Ludy Yohana - Ex-INVIMA Inspector & PIC/S Expert

Atul Tyagi- 25+ years of intense experience and professional expertise in the area of API Manufacturing, Qualification and validation and facilities management across assignments and also production planning.

Michele Lisa- QP, GMP expert based in Italy having 12+ years experience in Solid dosage, Sterile, Liquid and Medical devices

Dr. Vandana U. – 30+ years of experience in the pharmaceutical industry (Sterile Injectable/Ophthalmic/Oral Solid Dosages/ Oral Liquid Dosages/APIs: Sterile-Non-Sterile).

Our Key GXP Team

Sanjeev Patel & Geerish - CSV experts , 15+ years experienced SMEs.

Sandeep Patel- Regulatory affairs specialist having 13+ years experience. Expertise in DMF Life cycle management, eCTD dossier compilation, CEP/COA, USDMF, Tech pack, US agent appointment etc.

June H. - GMP expert based in China, rich 23 years in pharmaceutical industry

Dr. I. H. Siddqui -Our R&D expert having 30+ years rich experience in Research and Development (R&D). Dealing with Process development, Product mapping, Product optimization, Technology transfer, Controlled strategies of impurities, Impurity Structure elucidation report, Impurity profile and justification, Trouble shooting, Lab validation etc.

Rakesh Sutria. – GCP Head having 17+ years experience in Clinical research.

Zarna thakker- Quality consultant based in Canada.

Rameet K- Pharmacovigilance and Regulatory Expert

Jessica, Pranav Sid : - Quality auditor/consultant based in Mexico and USA.

Furuzwa- Quality Consultant based in Japan

G. Vala- GxP expert based in Spain. Skilled in Biotechnology, Pharma, RA. Strong quality professional.

Why Pharmexpert Consultant ?

PHARMEXPERT

ONE STOP SOLUTION

With Global presence, we Positioned our self as Qualified company with one stop solution for companies worldwide

GLOBAL COVERAGE

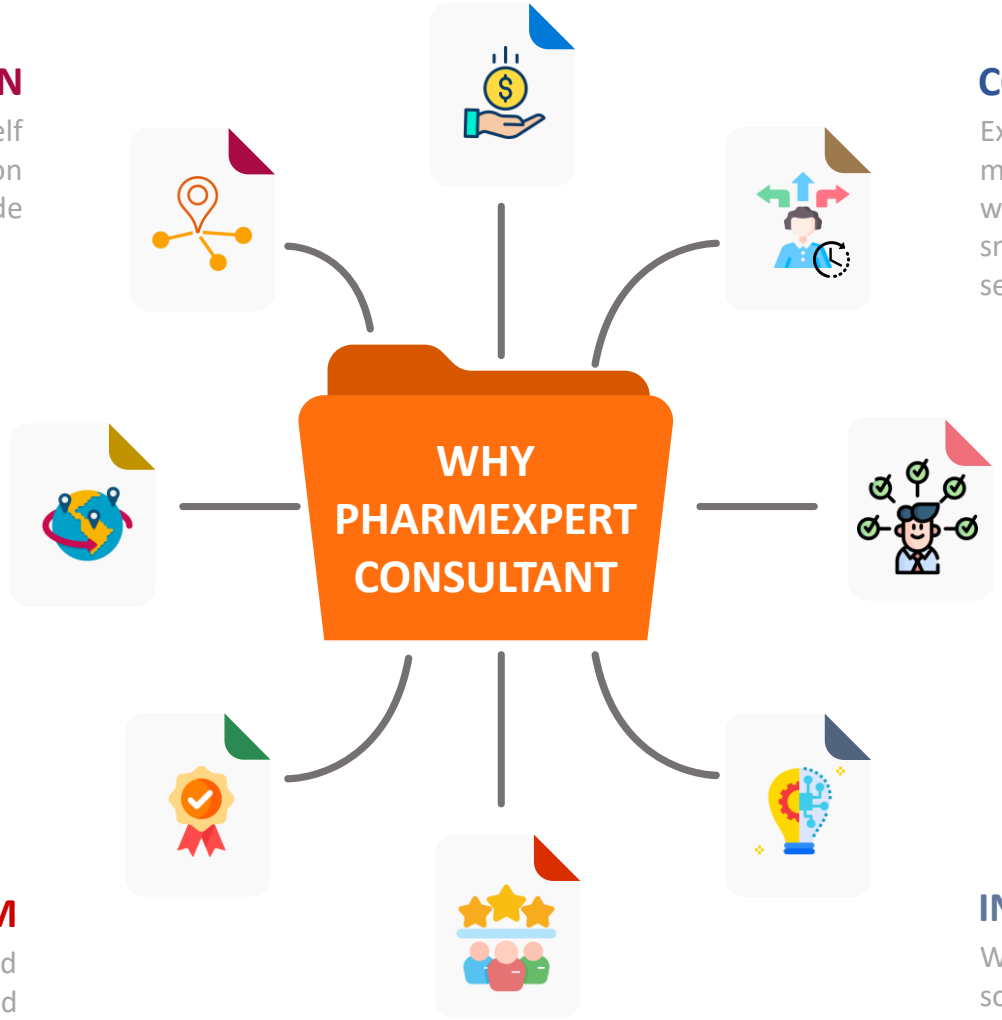
Wide geographical coverage throughout India. Europe, North and South America, the Middle East, China Japan, etc., we can execute audits in every location.

QUALITY SYSTEM

ISO 9001 Certified
Audit report template for high-quality results, Consultants/ Auditors Training with Absence of Conflict of Interest, Fulfilment of the audit life cycle Confidentiality for all parties, Trustworthiness evaluation

EXPERIENCED TEAM

A team with over 1000 projects completed worldwide. Auditors/Consultants are trained and qualified as per Pharmexpert methodology.



COST EFFECTIVENESS

Exceptional focus on cost effectiveness, while maintaining the highest quality standards.
we have a client base varies from top MNCs to small companies as all of them can afford our services.

FLEXIBILITY & TIMELY DELIVERY

Flexibility in availability, timely completion and follow-up can be offered as versed with a large pool of consultants/ auditors and admin staff

PROACTIVE & POSITIVE ATTITUDE

Circumstances changes, and we are Positive and Proactive about changing circumstances

INNOVATION & CREATIVITY

We thrive ourselves to offer innovative solutions for Customer's need.

Thank You !

PHARMEXPERT

We Look forward to know Your requirements

India

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