KI Pharma Alliance GmbH

Your global **GxP & Market Entry Partner**

FOREWORD OF THE MANAGEMENT
Managing Director Joerg Kloppert, MBA

Based in the proximity of Vienna, one of the most prestigious historical places of Europe, KI Pharma Alliance GmbH started its business as a professional and efficient GMP & Regulatory Consulting company in 2008. We have been growing ever since, now also acting in product development and business networking in Asia, Middle East, Latin America and North America. Since 2010, we have been aligned with our licensing partner pharmavision GmbH, a pharmaceutical company based in Vienna with its distribution partners in EU countries. Since 2015, KI Pharma Alliance expanded its operations to Asia, having offices in Hong Kong, Thailand, Myanmar and the Philippines. After having acquired 100% of Pharmavision GmbH shares in 2017, we were able to sign Marketing and distribution alliances for Latin America and also Australia in 2018.

I founded KIPA in 2008 with the vision to combine available global pharmaceutical market know how, a global network, high profile GMP knowledge and a loyal team with a view to fulfill the increasing demand for high-class, lean and cost-efficient production and fully validated supply chains.

We are proud of having successfully achieved EU / PICs / WHO GMP certifications of several partners in South Korea, Bangladesh, India, Thailand, Myanmar, the Philippines etc.. KIPA along with its 100% owned Pharmavision GmbH, has already established a high-value licensing business for products manufactured at EU GMP certified sites. Our GMP consulting projects in the ASEAN region are developing fast and since 2012, we are proud to provide our expertise also to several Health ministry operations in this region.

A substantial segment of the KIPA success is the well-balanced technical R&D and regulatory expertise in combination with high-level GMP expertise, covering all key activities in Quality assurance, Quality Control, production and engineering. The huge amount of years of practical experience of our well-known experts and team players in this area is a perfect match with the huge pharmaceutical market, business development and project management expertise.
The technical and regulatory expert team is the technical interface between KIPA production partners and marketing partners.

Clients who benefit from the KI Pharma Alliance services are able to enhance their production efficiency, perfect their documentation, increase their development expertise and increase international business activities towards regulated markets in the European Union and other regions at the same time. Also, GMP and regulatory expertise with sourcing, site-transfer management, business development and global business can be chosen each as a separate dish from the overall KIPA service menu.

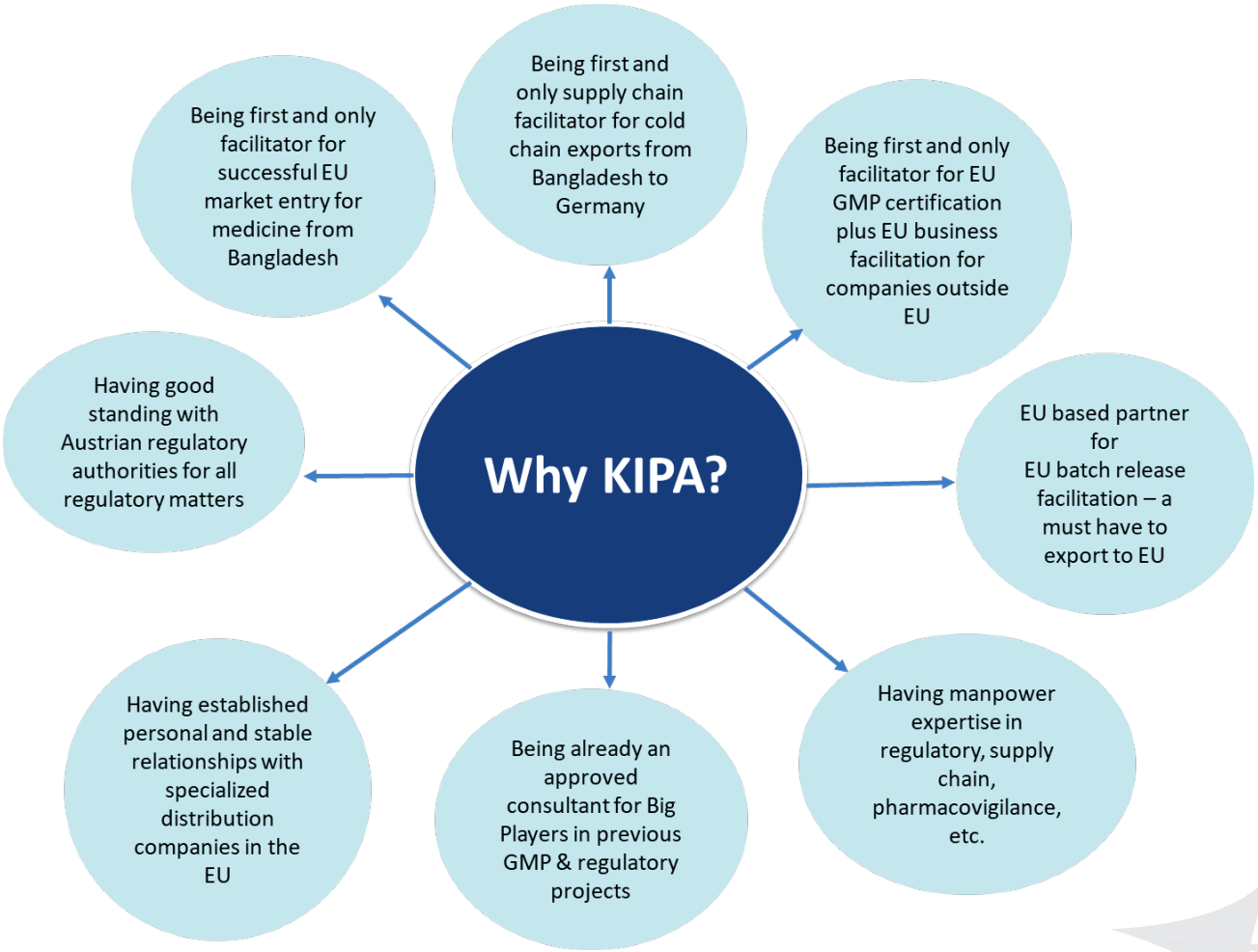
Find out what we can do for you. We will be delighted to provide our hands-on support and to include you in our network of valuable partners.

Sincerely,
Joerg Kloppert

- About KI Pharma Alliance Group
- The service portfolio
- Facility planning
- High level GMP consultancy up to GMP certifications
- Product Sourcing & Licensing
- Product Development,Analytical method and production process transfer, regulatory support for Market access

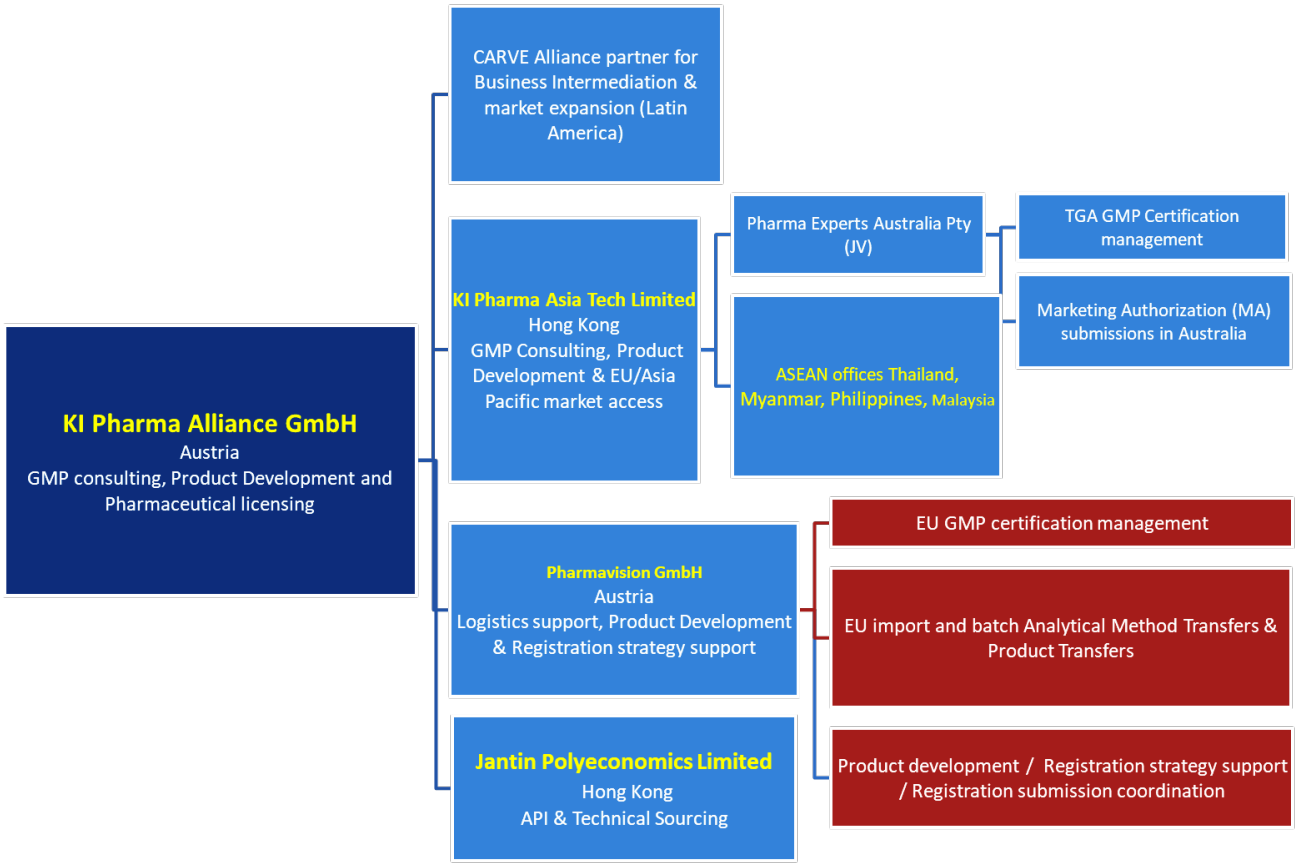
About the KI Pharma Group

You may ask „Why should we work with KI Pharma? There are plenty consultants out there promising everything.“ The simple answer is: Our KI Pharma experts only promise what we can deliver. And so far, we delivered 100% success projects.



This is the only reason, why we were able to grow in a stable and constant way. Another reason is certainly also the client proximity of our top professional experts in the areas of Quality Assurance, Quality Control, Sterile Production, Non-sterile production, Product development, Regulatory and Project Management.

With our today's regional structure set up, an onsite trouble-shooting availability of our experts within a 24-hour maximum planning cycle is in place and practice for our clients.



Remember:

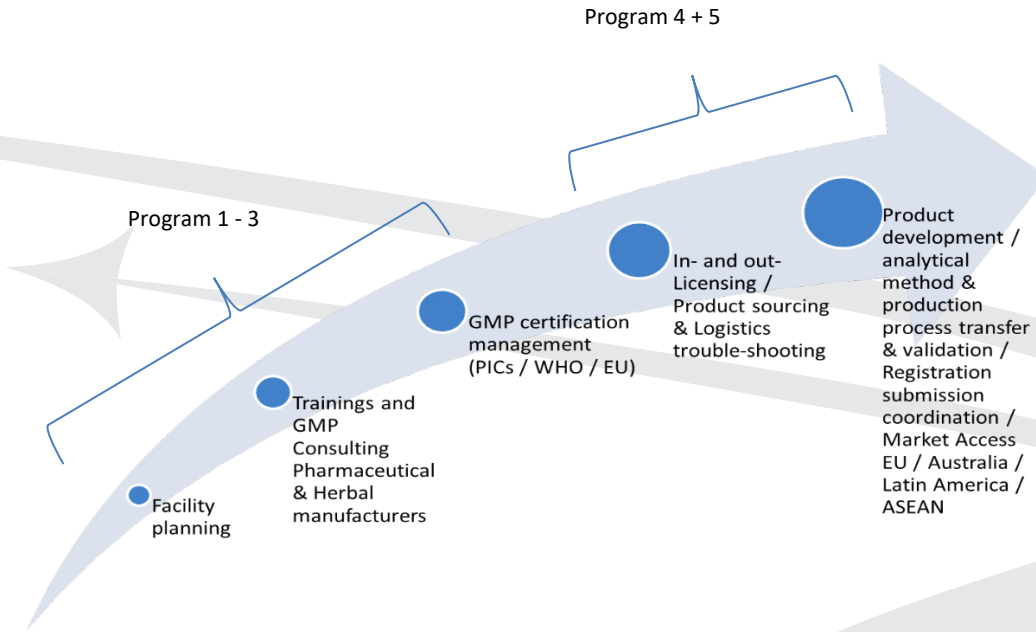
- ✓ KI Pharma experts deliver what we promise 100% for more than 10 years already
- ✓ KI Pharma experts are available for you within 24-hours from Europe, Asia, Australia and Latin America

Successful EU GMP certification project of Amherst Laboratories Inc., Philippines (Member of the United Laboratories Inc.)

The KI Pharma Group service portfolio

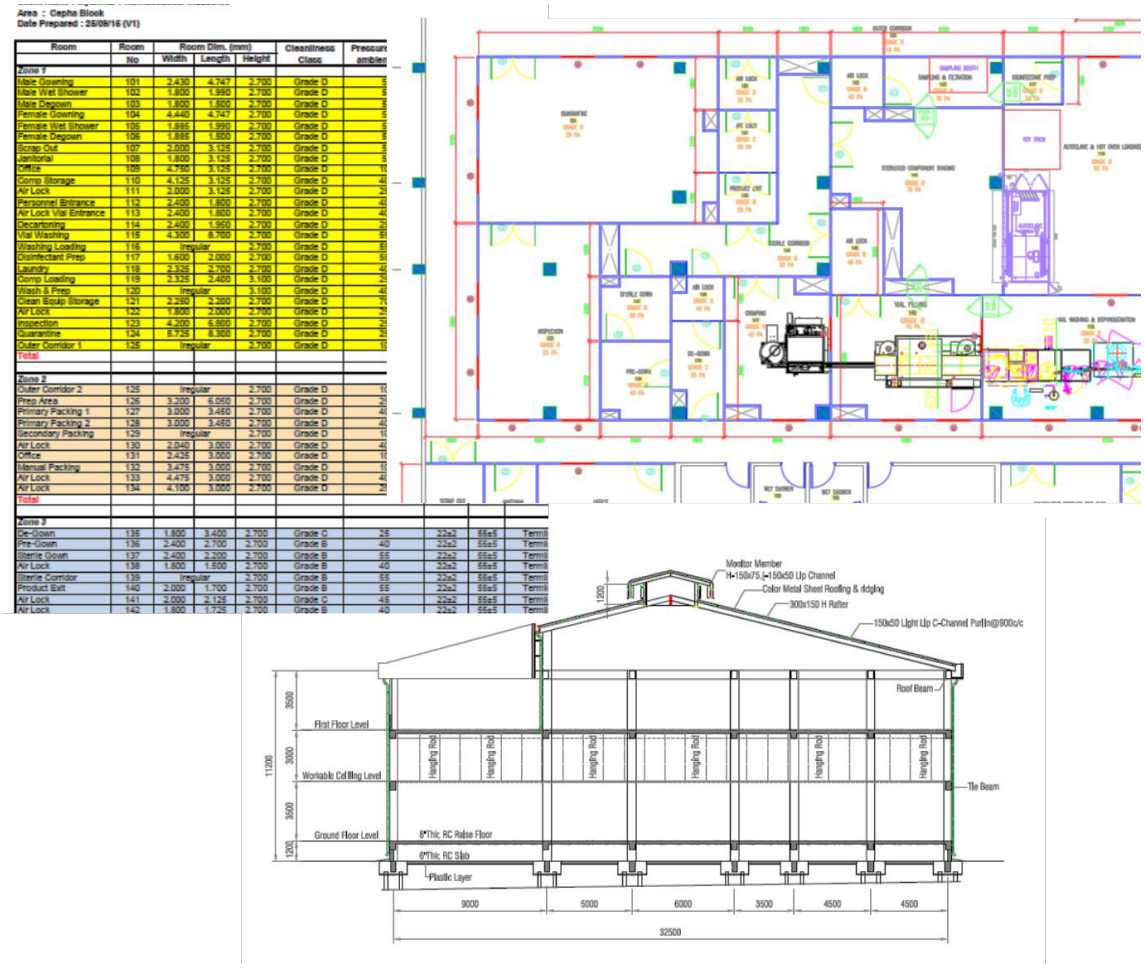
Program 1	Facility planning
Program 2	GMP Consulting & Training for Pharmaceutical & Herbal product manufacturers
Program 3	GMP Certification management for EU / PICs (TGA) / WHO GMP
Program 4	In-/Outlicensing and Product Sourcing & Logistics trouble shooting
Program 5	Product development / Analytical method and Process transfers & Validation / Registration submission coordination / Market Access EU / Australia / Latin America / ASEAN

Our service portfolio follows the typical lifecycle which a pharmaceutical manufacturer experiences. This allows us to offer our clients either separate programs or the full menu always based on the clients need.



Facility planning

Whether you have a greenfield project or an upgrading project, your facilities and your equipment and utilities set up must be planned in a proper and coordinated way.



Area : Cepha Block
Date Prepared : 26/08/15 (V1)

Room	Room No	Room Dim. (mm) Width	Length	Height	Cleanliness Class	Pressure (amb)
Zone 1						
Male Gowning	101	2,430	4,747	2,700	Grade D	5
Male Wet Shower	102	1,800	1,980	2,700	Grade D	6
Male Degown	103	1,800	1,800	2,700	Grade D	5
Female Gowning	104	4,440	4,747	2,700	Grade D	5
Female Wet Shower	105	1,885	1,950	2,700	Grade D	6
Female Degown	106	1,885	1,800	2,700	Grade D	5
Scrap Out	107	2,000	3,125	2,700	Grade D	5
Janitorial	108	1,800	3,125	2,700	Grade D	5
Office	109	4,750	3,125	2,700	Grade D	15
Comp Storage	110	4,125	3,125	2,700	Grade D	40
Air Lock	111	2,000	3,125	2,700	Grade D	20
Personnel Entrance	112	2,400	1,800	2,700	Grade D	40
Air Lock Vial Entrance	113	2,400	1,800	2,700	Grade D	40
Decartoning	114	2,400	1,950	2,700	Grade D	20
Vial Washing	115	4,300	8,700	2,700	Grade D	60
Washing Loading	116	Irregular		2,700	Grade D	60
Disinfectant Prep	117	1,800	2,000	2,700	Grade D	60
Laundry	118	2,325	2,700	2,700	Grade D	40
Comp Loading	119	2,325	2,400	3,100	Grade D	20
Wash & Prep	120	Irregular		3,100	Grade D	40
Clean Equip Storage	121	2,250	2,300	2,700	Grade D	70
Air Lock	122	1,800	2,000	2,700	Grade D	20
Inspection	123	4,200	6,800	2,700	Grade D	20
Quarantine	124	8,725	8,300	2,700	Grade D	20
Outer Corridor 1	125	Irregular		2,700	Grade D	10
Total						
Zone 2						
Outer Corridor 2	125	Irregular		2,700	Grade D	10
Prep Area	126	3,200	6,050	2,700	Grade D	20
Primary Packing 1	127	3,000	3,450	2,700	Grade D	40
Primary Packing 2	128	3,000	3,450	2,700	Grade D	40
Secondary Packing	129	Irregular		2,700	Grade D	10
Air Lock	130	2,040	3,000	2,700	Grade D	40
Office	131	2,425	3,000	2,700	Grade D	10
Manual Packing	132	3,475	3,000	2,700	Grade D	10
Air Lock	133	4,475	3,000	2,700	Grade D	40
Air Lock	134	4,100	3,000	2,700	Grade D	20
Total						
Zone 3						
De-Gown	135	1,800	3,400	2,700	Grade C	25	22±2	55±5	Termi
Pre-Gown	136	2,400	2,700	2,700	Grade B	40	22±2	55±5	Termi
Sterile Gown	137	2,400	2,000	2,700	Grade B	55	22±2	55±5	Termi
Air Lock	138	1,800	1,600	2,700	Grade B	40	22±2	55±5	Termi
Sterile Corridor	139	Irregular		2,700	Grade B	55	22±2	55±5	Termi
Product Exit	140	2,000	1,700	2,700	Grade B	55	22±2	55±5	Termi
Air Lock	141	2,000	2,125	2,700	Grade C	45	22±2	55±5	Termi
Air Lock	142	1,800	1,725	2,700	Grade B	40	22±2	55±5	Termi

When employing KI Pharma experts, you receive the KI Pharma equipment procurement evaluation assessment by applying our *KIPA Equipment Assessment Methodology*© on top of the regular design packages (Concept, Basic and Detail Design) or as a separate service in case you have already a design consultant. Our equipment assessment methodology uses questionnaires in combination with statistical methods which will be customized for each client.

- ✓ **Concept – Basic – Detail design**
- ✓ **Equipment procurement support**
- ✓ **Cleanroom performance testing (NEBB)**
- ✓ **Commissioning up to Validation supervision**

If required, KI Pharma can provide a complete cleanroom design and HVAC concept planning. Furthermore, and along with our engineering partners, we provide for our clients also an independent 3rd party cleanroom performance testing up to certification by an accredited NEBB engineer.

NEXTECH

NEBB

CERTIFICATE OF COMPLIANCE

PHARMACEUTICAL FACTORY (INSEIN)

CEPHALOSPORIN PRODUCTION PLANT
(GRADE B, C, D, & UNCLASSIFIED)

Test Condition : At Rest

As per requirement of EU GMP the designated area listed have met the respective acceptance criteria. Testing was performed as outlined in the above standard and the results are attested to it in the Report No: **316/CR-12/2016**

Nextech Sdn Bhd NEBB TAN CHEE KIAN CERTIFICATE 3144 Cleanroom Performance

Date of Certification : 11-15/12/2016 — Alvin Tan Chee Kian
Due Date : 11/12/2017 — CPT Certified Professional

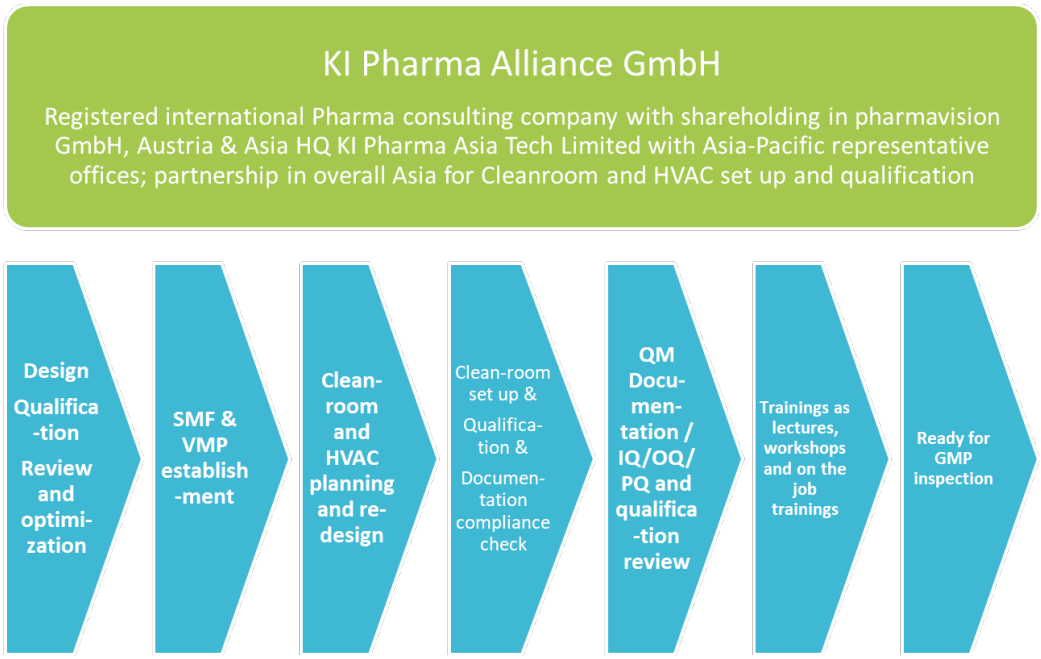
NEXTECH SDN. BHD.
19, Jalan Bukit Bandung 26/4, IHCOM Industrial Estate
40000 Shah Alam, Selangor Darul Ehsan, Malaysia.
Tel: 03-51923833 Fax : 03-51922088

Our expert team is also available during the construction, commissioning and validation phase and

can act as your appointed supervisor during this important GMP project phase up to facility completion.

GMP Consulting program

Our GMP Consulting program covers all detail compliance necessities to become certified by the relevant target authority. Our Consultant experts from Europe and Asia in the areas of Quality Assurance, Quality Control and Production are certified IRCA auditors all being trained in the EU.

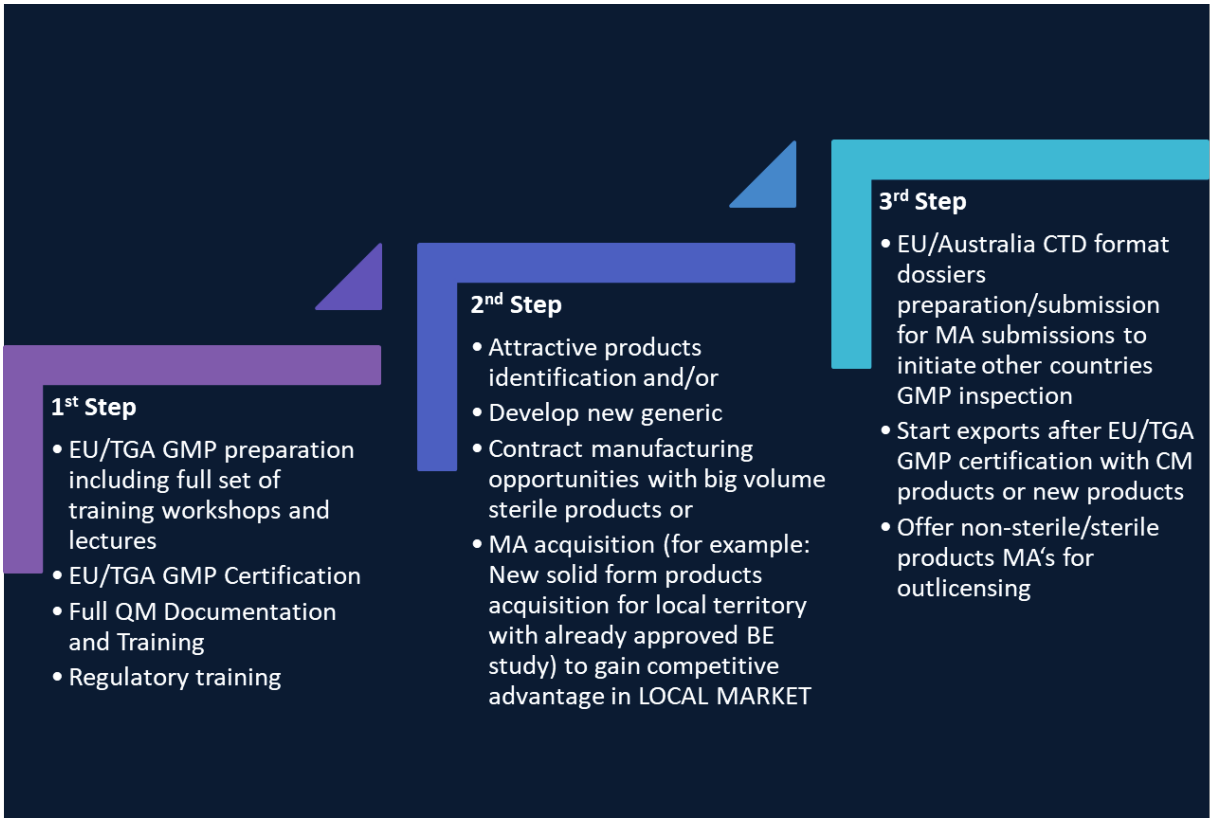


Depending on the target market, the relevant guideline will be applied and all key GMP compliance parameters will be checked and our team helps our clients to systematically comply in all relevant areas.

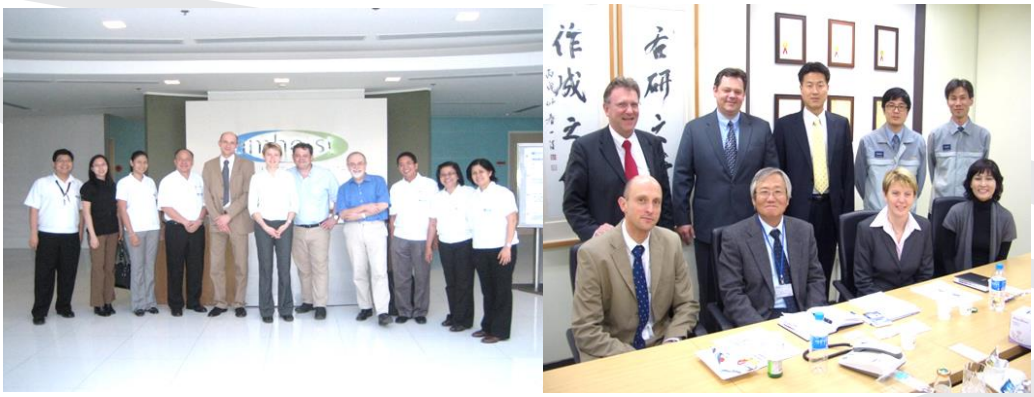
Your staff will be trained by our experienced and well educated trainers, covering from basic GMP trainings up to highly sophisticated operational excellence training sessions.

GMP Certification management

Your target is high level GMP compliance certification by either EU or TGA Australia authorities in order to boost your export and also your local business as a logical consequence of the excellence reputation? We will get you there with our 3-step approach.



With our set up structure in the EU and in Australia, we are able to manage the entire GMP certification process from A-Z.



Evidences of several successful completed projects show that we know what we are talking about. Remember: KI Pharma delivers what we promise!

Product In/Out-licensing, Product Sourcing & Logistics trouble-shooting

You are looking for an API with specific impurity profile or bulk density or a finished product which fits in your therapeutic portfolio but your equipment set up does not support an own development? Talk to us! Our KI Pharma product license database is maintained since the beginning of our Consulting activities in 2008.

KIPA*pedia*

KIPApedia	KIPA Knowledge Database. *Organize and keep track of the accumulated knowledge of your colleagues and yourself.* *Everyone with a valid network account can read, check with your admin if you need write access.*

API SOURCING

Active Substance	Therapeutical Class	Supplier Region
ALENDRONATE SODIUM	Bone Calcium Regulat	Spain China India -
ALPRAZOLAM USP	Tranquillisers	USA Italy Benelux

	EI CalQtr/12/2011 (Tausend)	EI CalQtr/12/2011 +/- % Vorherige Periode (Absolut)	EI CalQtr/12/2011 V% (Absolut)	EI 6Month/12/2011 (Tausend)	EI 6Month/12/2011 +/- % Vorherige Periode (Absolut)	EI 6Month/12/2011 V% (Absolut)	EI MAT/12/2011 (Tausend)	EI MAT/12/2011 +/- % Vorherige Periode (Absolut)	EI MAT/12/2011 V% (Absolut)	EURO CalQtr/12/2011 (Tausend)
A10 ANTIDIABETIKA	1.198,3	7,0	6,1	2.318,0	8,5	6,0	4.454,1	3,6	5,9	20.919
A10C HUMANINSULIN UND ANALOGA	300,4	7,1	25,1	581,0	9,7	25,1	1.110,9	0,8	24,9	9.406
A10C1 HUM.INSUL+ANALOG.SCHNELL	95,9	4,1	31,9	188,1	8,3	32,4	361,7	1,7	32,6	2.811
ACTRAPID	6,9	4,6	7,1	13,4	1,7	7,1	26,6	-6,4	7,3	190
APIDRA	3,9	-42,7	4,1	10,8	-10,5	5,7	22,8	-6,5	6,3	112
HUMALOG	20,5	11,5	21,4	38,9	7,1	20,7	75,1	0,3	20,8	619
HUMINSULIN NORMAL	0,8	3,6	0,8	1,6	-2,3	0,8	3,2	-6,2	0,9	20
INSUMAN INFUSAT	0,1	3,7	0,1	0,3	-3,2	0,1	0,6	-22,6	0,2	6
INSUMAN RAPID	1,7	3,8	1,7	3,2	-0,8	1,7	6,5	-9,0	1,8	45
NOVORAPID	62,0	7,2	64,7	119,9	12,1	63,8	226,9	4,7	62,7	1.818

All Finished Products have ICH stability data in relevant zone, clinicals and bioequivalence studies against its respective brand names products.

Batch sizes, CIF costing and license fee etc. can be provided once target markets are defined and upon achievable volumes are provided.

Product Development, Analytical method and production process transfer, regulatory support for market access

Your R&D department is overloaded with own new projects but you require further products to achieve your ambitous annual submission and launch targets? You experience trouble with your ongoing development products and either this product development will not be successful or other development products will be delayed? Your inlicensed product is no longer competitive in your market because of high import prices and you want to develop your own product and control all costs? Or you simply have to wait until your facility is ready before you can start with your own developments?

Talk to us! Here is what we can do for you:

WIth our 3 package services, we can provide to you:

- Technology transfer based on our own KI Pharma Product Dossiers (including analytical method and production process transfer including validation)
- Technology know how transfer based on our KI Pharma Product Technology packages (includes transfer of formulation and analytical method know how)
- Development support by utilizing our expert knowledge onsite in your facilities, developing the product you need on your behalf along with high level R&D training of your staff

KI Pharma expertise in Formulation Development Generics & OTC

- Strong hands on & managerial experience In development
- Pharmaceutical Concept Note, Formulation and Regulatory strategies
- Pre –formulation to Prototype Development
- Selection of CRO, Review of protocol and conducting equivalence studies
- Preparation of Technology Transfer Package
- Validation & Commercial batches
- Technology Transfer from R&D to Production
- Multi-Site Transfer
- One stop solution for Product Development
- Quality development with optimised Cost with competitive timelines
- Flexible Business Model
- Services as fully Integrated or Standalone i.e. (only concept, prototype , validation batches, submission or post submission)
- Recipe/ Formula Improvement
- Process Improvement
- Key staff mentioned as inventors in patent applications (Australia and worldwide)

KI Pharma R&D Experience in place for following Dosage Forms:

- **Oral Solids (Tablets & Capsules)**
- IR/ MR/ ER /SR/ODT
- Film/ Enteric/ Sugar coated
- Tablet in Tablet/ bi-Layer
- Capsules: hard, soft, tablet in caps
- **Topicals**
- Cream, Gel, Emulgel, Ointment and shampoos
- **Liquids**
- Syrup and Suspension
- **Sterile**
- Ophthalmic
- Nasal
- Injectable
- **Inhalers**
- Dry Powder (Capsule based and multidose unit)
- pMDI (single stage and double stage)

KI Pharma expertise in following Technologies

- Oral Thin Film, Spray
- Transdermal Patch
- Delayed Release MUPS (multiple unit pellet system)
- Hot Melt Technology
- Solubilization & Polymorphs

KI Pharma expertise for product developments catering following Markets through Development & Regulatory Expertise and submissions

- US (ANDA, FTF)
- EU
- Japan
- Australia
- Canada
- Brazil
- GCC
- WHO
- India
- Emerging Markets

KI Pharma – Regulatory Expertise

Experience in Application of Principles & Regulations

- QbD (Quality by Design)
- DoE (Design Of Experiments)
- GCP (Good Clinical Practice)
- GLP (Good Laboratory Practice)
- GMP (Good Manufacturing Practice)
- GVP (Good Pharmacovigilance Practices)

KI Pharma Authority Expertise

- Regulated Markets (USA, EU, Australia, Japan, Canada)
- WHO
- ANVISA
- GCC
- Emerging markets

KI Pharma Strategy & Regulation guidance in product development & lifecycle management of commercialized products

- Applicable regulatory Guidelines knowledge
- Dossier compilation, submission & approvals
- Query Handling / response to Deficiency letters
- PV compliances
- Facility Inspections & approval
- Establishment of R&D from concept to product approvals for regulated market business
- Training of scientist for product development and analytical method development
- Technology Transfer
- XRD and DSC techniques to study polymorphs

Example Project experiences

Molecule	Usage	Form	Strength	Normal Development time upto submission batches	Development time with KIPA upto submission batches	Developed for Markets on behalf of clients
Voglibose	Anti diabetic	Tablets	0.2 & 0.3 mg	30 months	16 months	Japan
Voglibose	Anti diabetic	OD Tablets	0.2 & 0.3 mg	30 months	16 months	Japan
Cetirizine	Anti allergic	Tablets	5 & 10 mg	30 months	14 months	Japan
Amlodipine	Antihypertensive	Tablets	2.5 & 5 mg	24 months	14 months	Japan
Amlodipine	Antihypertensive	OD Tablets	5 & 10 mg	30 months	16 months	Japan
Ceditoren	Anti infective	Tablets	100 mg	36 months	24 months	Japan
Carvedilol	Congestive Heart failure	Tablets	3.125, 6.25, 12.5 & 25 mg	30 months	16 months	USA
Sotalol	Atrial flutter	Tablets	80, 120 & 160 mg	30 months	16-18 months	USA
Sotalol AF	Heart flutter	Tablets	80, 120 & 160 mg	30 months	16-18 months	USA
Methocarbamol	Muscle relaxant	Tablets	500 & 750 mg	30 months	16 months	USA
Metformin	Anti diabetic	ER Tablets	500 & 750 mg	30 months	16 months	USA

Molecule	Usage	Form	Strength	Normal Development time upto submission batches	Development time with KIPA upto submission batches	Developed for Markets on behalf of clients
Cyproheptadine	Anti histamine	Tablets	4 mg	28 months	14 months	USA
Nadolol	Angina & BP	Tablets	20, 40 & 80 mg	36 months	18-20 months	USA
Flecainide	Cardiac arrythmia	Tablets	50, 100 & 150 mg	30 months	16 months	USA
Baclofen	Muscle relaxant	Tablets	10 & 20 mg	24 months	16 months	USA
Hydroxychloroquine	Anti malarial	Tablets	200 mg	30 months	18 months	USA
Minocycline	Anti infective	Tablets	50, 75 & 100 mg	30 months	20 months	USA
Oxybutynin	Urinary incontinence	Tablets	5 mg	30 months	20 months	USA
Metronidazole	Anti protozoal	Tablets	250 & 500 mg	30 months	16 months	USA
Sitagliptin	Anti diabetic	Tablets	25, 50 & 100 mg	28 months	16 months	USA
Sitagliptin + Metformin	Anti diabetic	Tablets	50/850, 50/l000 mg	30 months	16 months	USA
Clarithromycin	Anti infective	Tablets	250 & 500 mg	30 months	16 months	USA
Nebivolol	Anti hypertensive	Tablets	2.5, 5, 10 & 20 mg	36 months	18 months	USA

Molecule		Form	Strength	Normal Development time upto submission batches	Development time with KIPA upto submission batches	Developed for Markets on behalf of clients
Clopidrogel	Anti blood clots	Tablets	75 mg	30 months	16 months	EU
Citalopram	Anti depressant	Tablets	10, 20 & 40 mg	24 months	16 months	EU
Escitalopram	Anti depressant	Tablets	5, 10 & 20 mg	24 months	16 months	EU
Olanzapine	Anti depressant	Tablets	2.5, 5, 7.5, 10, 15 & 20 mg	30 months	18 months	EU
Olanzapine	Anti depressant	OD Tablets	5, 10, 15 & 20 mg	30 months	18 months	EU
Paroxetine	Anti depressant	Tablets	20 & 40 mg	30 months	20 months	EU
Piracetam	Improve cognitive functon	Tablets	800 mg	24 months	16 months	EU
Quetiapine	Anti psychotic	Tablets	25, 50, 100, 150, 200, 300 mg	28 months	16 months	EU
Esomeprazole	Acid regulator	MUPS Tablets	20 & 40 mg	48 months	30 months	EU
Pantoprazole	Acid regulator	Tablets	20 & 40 mg	30 months	16 months	EU; USA; LATAM
Levofloxacin	Anti infective	Tablets	250 & 500 mg	24 months	14 months	EU
Telmisartan	Anti hypertensive	Tablets	40 & 80 mg	36 months	24 months	EU
Telmisartan + HCT	Anti hypertensive	Tablets	40/12.5, 80/12.5 mg	36 months	24 months	EM

Molecule	Usage	Form	Strength	Normal Development time upto submission batches	Development time with KIPA upto submission batches	Developed for Markets on behalf of clients
Zolpidem	Insomnia	Tablets	5 & 10 mg	24 months	16 months	EU
Irbesartan	Hypertension	Tablets	150 & 300 mg	28 months	16 months	EU
Irbesartan + HCT	Hypertension	Tablets	150&300/12,5 mg	28 months	18 months	EU
Gliclazide	Anti diabetic	MR Tablets	30 mg	40 months	20 months	EU
Olmesartan	Hypertension	Tablets	10, 20 & 40 mg	28 months	18 months	EU
Olmesartan + HCT	Hypertension	Tablets	20/12.5, 40/12.5 & 40/25 mg	30 months	20 months	EM
Valsartan	Hypertension	Tablets	80, 160 & 320 mg	28 months	18 months	LATAM
Valsartan + HCT	Hypertension	Tablets	80, 160, 320 /12.5 mg	30 months	20 months	LATAM
Bisoprolol	Hypertension	Tablets	5 & 10 mg	24 months	18 months	South Africa
Bisprolol + HCT	Hypertension	Tablets	5/12.5 & 10/25 mg	24 months	18 months	South Africa
Ondansetron	Anti emetic	Oral thin film	4 & 8 mg	40 months	30 months	EM
Trimetazidine	Angina pectoris	MR Tablets	35 mg	36 months	22 months	EM
Paracetamol	Antipyretic	ER Tablets	665 mg	36 months	18 months	EM

Molecule	Usage	Form	Strength	Normal Development time upto submission batches	Development time with KIPA upto submission batches	Developed for Markets on behalf of clients
Donepezil	Dementia	Tablets	5 & 10 mg	30 months	16 months	Brazil
Erythromycin	Anti acne	Gel	2%	24 months	16 months	EM
Piroxicam	Analgesic	Gel	0.5 %	30 months	16 months	Brazil
Piroxicam	Analgesic	OD Tablets	20 mg	24 months	16 months	Brazil
Azithromycin	Anti infective	Tablets	250 & 500	30 months	18 months	Brazil
Ketaconazole, Betamethasone	Anti fungal	Cream & Oint	2 % and 0.05%	30 months	18 months	Brazil
Ketaconazole, Betamethasone & Neomycin	Anti fungal	Cream & Oint	2 %, 0.05 and 1 %	30 months	18 months	Brazil
Ketoconazole	Anti fungal	Shampoo	2 %	36 months	18 months	TT for Global Co
Dclofenac	Analgesic	Gel	1%	24 months	16 months	EM
Salbutamol	Asthama	Inhaler	100 mcg	48 months	30 months	EM
Tiotropium	COPD	Inhaler	18 mcg	48 months	26 months	EM

Molecule	Usage	Form	Strength	Normal Development time upto submission batches	Development time with KIPA upto submission batches	Developed for Markets on behalf of clients
Olopatadine	Allergy	Eye drops	0.1%	30 months	16 months	Canada
Moxifloxacin	Anti infective	Eye drops	0.5%	30 months	16 months	Canada
Bimatoprost	Glaucoma	Eye drops	0.03 %	30 months	18 months	EM
Levofloxacin	Anti infective	Eye drops	0.5%	30 months	18 months	EM
Chloramphenicol	Anti infective	Eye drops	0.5%	30 months	18 months	Australia
Cetirizine	Anti allergy	Oral liquid	5 mg / 5 ml	24 months	16 months	EM
Terbutaline	Anti asthma	Oral liquid	1.5 mg / 5 ml	24 months	18 months	Local

Please note that all above products have been developed earlier & we are aware about the criticality of each product in terms of stability issue, right polymorph, dissolution, particle size etc, so we can fast track now.

Notes:

KI Pharma Alliance GmbH