K-GMP 한국의료산업품질경영연구원

Korea Medical Industry Institute of Goods Management Procedure

Global Regulatory Affairs Consulting

K-GMP provides MFDS, FDA, CE, NMPA, ASEAN and Global Institute Regulatory compliance assistant for Companies in the Food, Cosmetic, Medical Device and Drug industries.

㈜한국지엠피는 K-GMP는 식품, 화장품, 의료기기 및 의약품 산업에 서비스, 정부 지원, 교육 및 훈련, 컨설팅 및 GMP 통역 사업을 기반으로 합니다. K-GMP는 고객에게 최고의 서비스를 제공하고 재능과 전문성을 통해 인류 사회에 공헌하고자 합니다.

K-GMP possess based on service, government support, education & training, consulting and GMP interpretation businesses in the Food, Cosmetic, Medical device and Drug industry. K-GMP would like to provide the best services for customers and contributes to the human society through talents and expertise.

Specialized consultants
From each industry

Supported by
Government agency

Global network with
About 150 countries agency

1: 1 company
Customized consulting

Global Registration & Regulatory Affairs Consulting

K-GMP는 북미, 남미, 유럽, 유라시아, 아세안을 포함한 아시아 국가 등 약 150여 개 국가의 컨설팅 전문 기관과 전략적 업무를 체결하고 글로벌 네트워크를 구축함으로써 식품, 화장품, 의료기기 및 의약품 산업의 고객사에게 전문성과 신뢰성을 바탕으로 발 빠른 글로벌 인증서비스를 제공해 드리고자 합니다.

K-GMP have conclude MOU and strategic consulting organization in more than 150 countries in North America (US, Canada), South America(Brazil, Colombia, Mexico, etc.), Europe, Eurasia (Russia, Ukraine, etc.) and Asia (China, Japan, ASEAN, etc.). K-GMP will provide fast and exact global regulatory affairs consulting based on our expertise and reliability with our global network to clients in Food, Cosmetic, Medical Device and Drug.

K-GMP 한국의료산업품질경영연구원 Korea Medical Industry Institute of Goods Management Procedure
www.K-GMP.com I http://blog.naver.com/kgmpcom I E-mail : K-GMP@K-GMP.com I Tel : +82 31 548 0055 I Fax : +82 505 369 0055

K-GMP

Global Regulatory Affairs Consulting

New creative & New challenge with Korea Medical Industry Institute of Goods Management Procedure

K-GMP One Stop Service

한 번 의뢰로 수출까지 일사천리!

All step service for export on one request!

계약 및 제품분석

Contract & GAP Analysis
Preliminary Evaluation (PE)

- Ingredients and product suitability
- Product classification and related regulations

등록 및 인증

Establishment & Product registration and Certificate

- Establishment & Product Registration / Notification
- Label Review
- Test report
- DOC (Declaration of Conformity)
- Documentation
- Certificate

수출입 통관

Import and export customs clearance

- Prior Notice
- Detention Assistance
- Inspection Assistance

성공 비즈니스 모델 개발

사전 제품&규제 검토를 통한 안정적인 수출입 성공사례 창출 및 지속적인 수출입 유지를 위한 사후관리 지원

계약 체결

인증 지원

- 수출입 적합성 검토
- 정부 국가지원사업 안내
  - 중소벤처기업부
  - 한국식품연구원
  - KOTRA

수출정보 제공

- 국가 유관기관 업무지원
  - TBT 화장품 자문위원
  - KITA 해외인증 자문위원
- 해외수출인증 정보 안내
  - www.K-GMP.com
  - blog.naver.com/kgmpcom

인력 개발

- GMP, ISO, FSMA 등 기업 교육 지원
- 할랄, 유기농 등 해외 인증 교육 지원
- 해외인증 세미나 지원

품질 관리

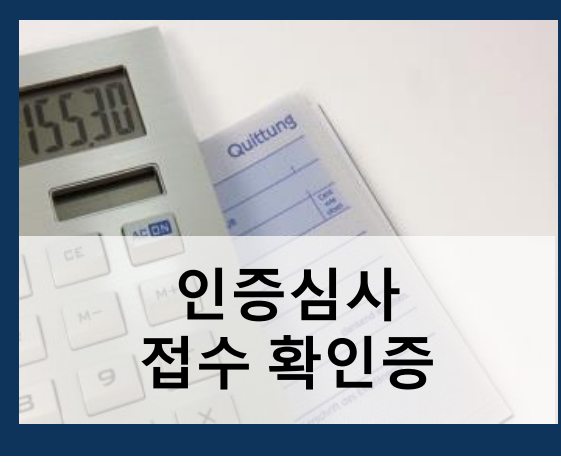
- GMP, ISO, FSMA 등 품질관리시스템 사전심사 및 전문통역 지원
- 제 3자기관 심사 및 보고서 지원

- ***한국지엠피(K-GMP)의 특별 서비스!!***

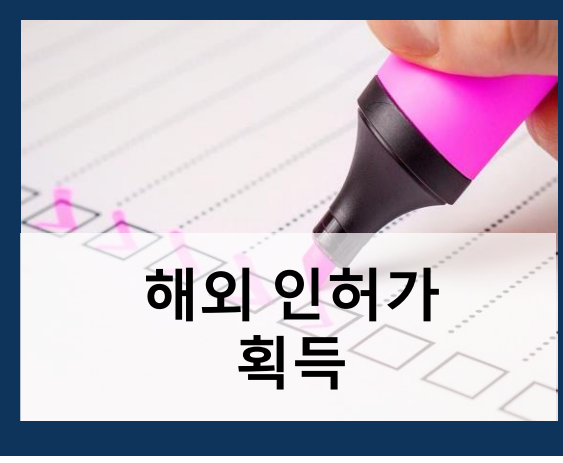
한국지엠피는 기업의 최소 비용, 최대 효율 창출을 돕기 위하여 1) 사업계획서 2) 해외 시장조사 3) 인증심사 접수 확인증 등의 업무를 제공하여 인증 획득의 정당성을 확보하고 국가지원사업 지원 시 가점을 받도록 돕습니다. 한국지엠피는 지원사업 선정부터 인증심사 후 인증서 발급까지 고객사의 원활한 수출을 위해 항상 고객사의 편에 서있습니다.

사업계획서 작성
(인증 획득의 필요성)

해외 시장조사
(인증 획득의 필요성)



인증심사
접수 확인증



해외 인허가
획득

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K-GMP

MFDS Regulatory Affairs Consulting

K-GMP will give you a quick and accurate advice on the MFDS regulation, licensing and certifying

식품의약품안전처
MINISTRY OF FOOD AND DRUG SAFETY

Ministry of Food and Drug Safety (MFDS) regulates food, cosmetic, medical device and drug intended for consumption in Republic of Korea by humans. K-GMP provides Registration, Responsible Agent, and Regulatory Compliance Assistance for companies importing to Korea in these industries.

FOOD & Functional Health Food

- Food Manufacturer Registration
- Food and Supplement Labeling and Ingredients Review
- Documentation
- Livestock regulation
- Food Self-qualified Test Assistant
- New Dietary Ingredients (NDI)
- Functional claim & Advertisement review
- Traceability management system

COSMETIC & Functional cosmetic

- Manufacturer Registration
- Cosmetic Labeling and Ingredients Review
- Cosmetic Ingredient List Report
- Documentation
- Prior Notice
- Responsible Agent Requirements

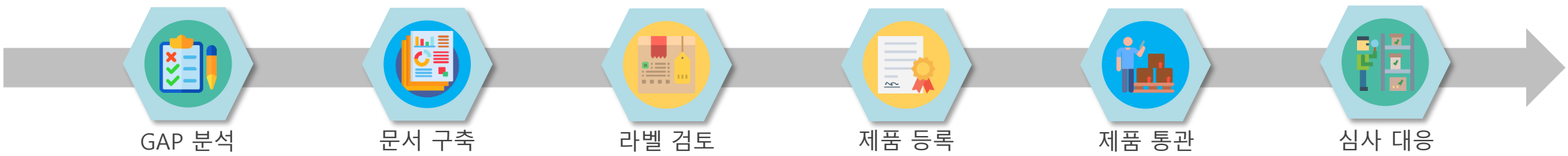
MEDICAL DEVICE

- Medical Device Establishment Registration and Listings
- Responsible Agent Requirements
- STED
- Medical Device Master Files (MAF)
- Life Cycle Risk Management
- Usability Assessment
- Cyber Security Assessment
- Unique Device Identifier (UDI) and Global Unique Device Identifier Database (GUDID)
- Medical Device Labeling and Product Reviews

OTHERS

- Certificate of MFDS Registration issued by K-GMP
- Detention Without Physical Examination ("DWPE") Assistance
- Food Safety Services; HACCP
- cGMP (Food, Cosmetics, Medical device) Service
- MFDS Inspection Interpretation Service
- K-GMP Mock Inspection Service by MFDS Inspection Rule

*Certificates of Registration or Reports issued by K-GMP provide confirmation to industry that you are fulfilling MFDS registration or regulation requirements.
**K-GMP is not affiliated with the MFDS.



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K-GMP

U.S. FDA Regulatory Affairs Consulting

K-GMP will give you a quick and accurate advice on the U.S. FDA regulation, licensing and certifying

FDA U.S. FOOD & DRUG ADMINISTRATION

The U.S. Food and Drug Administration (FDA) regulates food, cosmetics and medical device intended for consumption in the United States by humans or animals. K-GMP provides Registration, U.S. Agent, and Regulatory Compliance Assistance for U.S. and Non-U.S. companies in these industries.

FOOD & DIETARY SUPPLEMENT for Human & Animal

- Food Facility Registration (FFR) and U.S. Agent Requirements
- Food Canning Establishment (FCE) & Process Filings (SID)
- Food and Supplement Labeling and Ingredients Review
- U.S. State Bottled Water Requirements
- Food Contact Substances (FCS)
- Generally Recognized as Safe (GRAS)
- New Dietary Ingredients (NDI)
- FSMA & PCQI
- Prior Notice (Sending Imported Food to the USA)
- USDA Service and Label Approval Requirements

COSMETIC & OTC

COSMETICS

- Cosmetic Labeling and Ingredient Review
- Voluntary Registration System for Cosmetic Products (VCRP)
- California Safe Cosmetics Act Reporting (CSCP)

Over The Counter (OTC)

- Data Universal Numbering System (D-U-N-S®)
- Drug Establishment Registration (FEI Number)
- National Drug Code(NDC) & Product Registration
- OTC Labeling and Ingredients Review (OTC Monograph)
- New Drug Application(NDA)

MEDICAL DEVICE

- Data Universal Numbering System (D-U-N-S®)
- Medical Device Establishment Registration and Listings
- 510(k)
- Medical Device Master Files (MAF)
- Life Cycle Risk Management
- Usability Assessment
- Cyber Security Assessment
- Unique Device Identifier (UDI) and Global Unique Device Identifier Database (GUDID)
- Medical Device Labeling and Product Reviews

OTHERS

- Certificate of U.S. FDA Registration issued by K-GMP
- Detention Without Physical Examination ("DWPE") Assistance
- Food Safety Services; HACCP & FSMA
- cGMP (Food, Cosmetics, Medical device) Service
- U.S. FDA Inspection Interpretation Service
- U.S. EPA; Establishment Registration, Product Analysis
- K-GMP Mock Inspection Service by FDA Inspection Rule

*Certificates of Registration or Reports issued by K-GMP provide confirmation to industry that you are fulfilling U.S. FDA registration or regulation requirements. U.S.
**FDA does not issue or recognize Certificates of Registration.
***K-GMP is not affiliated with the U.S. Food and Drug Administration.

GAP 분석 **GAP Analysis** → 문서 구축 **Documentation** → 라벨 검토 **Label review** → 제품 등록 **Registration** → 제품 통관 **Customs clearance** → 심사 대응 **Facility Audit**

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EU Regulatory Affairs Consulting

K-GMP will give you a quick and accurate advice on the EU regulation, licensing and certifying

European Union (EU) regulates by an integrated regulation regarding food, cosmetics and medical device intended for consumption in the Europe by humans or animals.

FOOD & DIETARY SUPPLEMENT for Human & Animal

- Ingredients Compliance with EFSA
- Food and Supplement Labeling compliance
- Evaluation certificate of Food Label
- Novel food
- Food for Special Medical Purpose (FSMP)
- Food Contact Materials(FCM)
- Feed & Pet food

COSMETICS

- Cosmetic Labeling and Ingredient Review
- Cosmetic Product Notification Portal (CPNP notification)
- Acting as the Responsible person (RP)
- Product Information File (PIF) preparation
- Stability and compatibility test
- Challenge test
- Safety assessment (CPSR)
- Certificate of CPNP Registration issued by K-GMP

MEDICAL DEVICE

- EU MDR(Medical Device Regulation); MDD(Medical Device Directive) & AIMDD(Active Implanted Medical Device Directive)
- Life Cycle Risk Management
- Usability Assessment
- Cyber Security Assessment
- Unique Device Identifier (UDI) and Global Unique Device Identifier Database (GUDID)
- Medical Device Labeling and Product Reviews

OTHERS

- Detention Without Physical Examination ("DWPE") Assistance
- CE Mark; Electromagnetic Compatibility(EMC), Energy-using products(EUPs), Low Voltage Directive(LVD), Radio Equipment Directive(RED), Toy Safety Directive and etc.
- EU Declaration of Conformity
- Technical Document
- Quality Management System(GMP, ISO) Service
- K-GMP Mock Inspection Service
- ISO Inspection Interpretation Service

*Certificates of Registration or Report issued by K-GMP provide confirmation to industry that you are fulfilling EU registration or regulation requirements.
**K-GMP is not affiliated with the European Authority.

GAP 분석 **GAP Analysis** → 문서 구축 **Documentation** → 라벨 검토 **Label review** → 제품 등록 **Registration** → 제품 통관 **Customs clearance** → 심사 대응 **Facility Audit**

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NMPA Regulatory Affairs Consulting

K-GMP will give you a quick and accurate advice on the NMPA regulation, licensing and certifying

国家药品监督管理局
National Medical Products Administration

国家市场监督管理总局
State Administration for Market Regulation

The National Medical Products Administration (NMPA) regulates food, cosmetics and medical device intended for consumption in the China by humans. K-GMP provides Registration, Responsible Person, and Regulatory Compliance Assistance for China and Non-China companies in these industries.

FOOD & NUTRITIONAL SUPPLEMENT for Human & Animal

- Overseas Manufacturer Registration
- Ingredients Compliance Review with GB standard
- Chinese Label Review and Design
- Infant Formula & Nutritional Supplement Registration
- Food for Special Medical Purpose(FSMP) Registration
- New Food Additive Registration
- Filing for Infant Formula & Nutritional Supplement & FSMP
- Food contact materials(FCM)
- Customs Clearance Assistance(GB compliance test monitoring & HS code identification)

COSMETICS

- Cosmetic Labeling and Ingredient Review
- Non-special Use Cosmetics (Non-SUC) Notification
- special use cosmetics (SUC) Registration
- New Cosmetic Ingredients Registration
- Responsible Agent for Special Use Cosmetics
- Product Document Filling
- Product Test Arrangement and Supervision

MEDICAL DEVICE

- NMPA Filing & Registration
- Technical Document
- The identification document for product innovation(IP report)
- The safety and risk management report of product
- Unique Device Identifier (UDI) and Global Unique Device Identifier Database (GUDID)
- Authorized Representative (AR) in china
- Medical Device Labeling and Product Reviews

OTHERS

- Detention Without Physical Examination ("DWPE") Assistance
- China Pesticide & Disinfectants Regulation; Comprehensive analysis report, Labeling and Registration
- Technical Document
- Quality Management System(GMP, ISO) Service
- K-GMP Mock Inspection Service
- NMPA Inspection Interpretation Service

*Certificates of Registration or Report issued by K-GMP provide confirmation to industry that you are fulfilling NMPA registration or regulation requirements.
**K-GMP is not affiliated with the NMPA.

GAP 분석 **GAP Analysis** → 문서 구축 **Documentation** → 라벨 검토 **Label review** → 제품 등록 **Registration** → 제품 통관 **Customs clearance** → 심사 대응 **Facility Audit**

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ASENA Regulatory Affairs Consulting

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ASSOCIATION OF SOUTHEAST ASIAN NATIONS

ASEAN regulates by an integrated regulation regarding cosmetic and medical device intended for consumption in the ASEAN. Increasingly, the product range of the integrated regulation is expanding. K-GMP provides Regulatory Compliance Assistance for ASEAN companies in these industries.

FOOD & DIETARY SUPPLEMENT for Human & Animal

- ASEAN Food Safety Policy (AFSP) Compliance
- Food and Supplement Labeling and Ingredients Review
- Product Registration / Notification to Related Authority
- Traditional Medicines and Health Supplement
- Food Contact Materials(FCM)
- Feed & Pet food

COSMETICS

- ASEAN Cosmetic Directive(ACD) Compliance
- Acting as the Responsible person (RP)
- Product Notification
- Product Information File (PIF) preparation
- Stability and compatibility test
- Challenge test
- Safety assessment (CPSR)
- Certificate of CPNP Registration issued by K-GMP

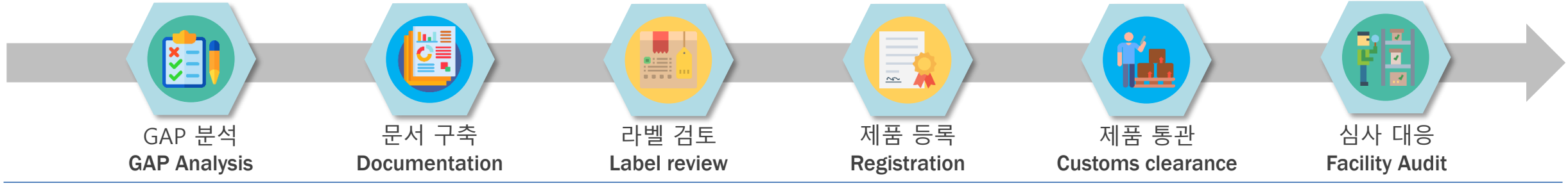
MEDICAL DEVICE

- ASEAN MEDICAL DEVICE DIRECTIVE (AMDD) Compliance
- ASEAN Common Submission Dossier Template (CSDT)
- Life Cycle Risk Management
- Usability Assessment
- Cyber Security Assessment
- Unique Device Identifier (UDI) and Global Unique Device Identifier Database (GUDID)
- Medical Device Labeling and Product Reviews

OTHERS

- Detention Without Physical Examination ("DWPE") Assistance
- Declaration of Conformity
- Technical Document
- Quality Management System(GMP, ISO) Service
- K-GMP Mock Inspection Service
- ISO Inspection Interpretation Service

*Certificates of Registration or Report issued by K-GMP provide confirmation to industry that you are fulfilling ASEAN registration or regulation requirements.
**K-GMP is not affiliated with the ASEAN Authority.



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Quality Management System Consulting

K-GMP will try to be more stabilized Quality management system such as GMP and ISO to be established.

K-GMP는 기업의 재정적 부담을 최소화하고 체계적인 교육 시스템으로 성장할 수 있도록 RA & QC 파견 업무 서비스를 제공합니다.

K-GMP has been providing companies with RA&QC dispatch work to minimize their financial burden and eventually to help them grow up under well-organized education system.

HACCP (Hazard Analysis and Critical Control Points)

식품의 원재료 생산에서부터 최종 소비자가 섭취하기 전까지 각 단계에서 생물학적, 화학적, 물리적 위해요소가 식품에 혼입되거나 오염을 방지하기 위한 위생관리 시스템

This is a preventative food safety system in which every step in the manufacture, storage and distribution of a food product is scientifically analyzed for microbiological, physical and chemical hazards. Potential hazards are, therefore, identified and appropriate control measures are taken before the problem can occur.

GMP (Good Manufacturing Practices) & Quality Management System(ISO)

식품, 화장품, 의료기기 및 의약품의 안정성과 유효성을 품질면에서 보증하는 기본조건으로서 우수 제조관리 기준

This is the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of food, cosmetic, medical device and drug. These guidelines provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use.

K-GMP SERVICE

사전심사	시정/예방조치 안내	현장심사 대응	사후관리
MOCK INSPECTION	Corrective Action & Preventive Action (CAPA)	AUDIT ASSISTANT	POST MANAGEMENT
	• Facility Regulation Advisory • Quality management documentation	• Inspection • Correspondence/Interpretation	• Inspection report by 3rd party

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GLOBAL Standard Documentation Consulting

K-GMP will give you a quick and accurate advice on the Global standard regulation and documentation.

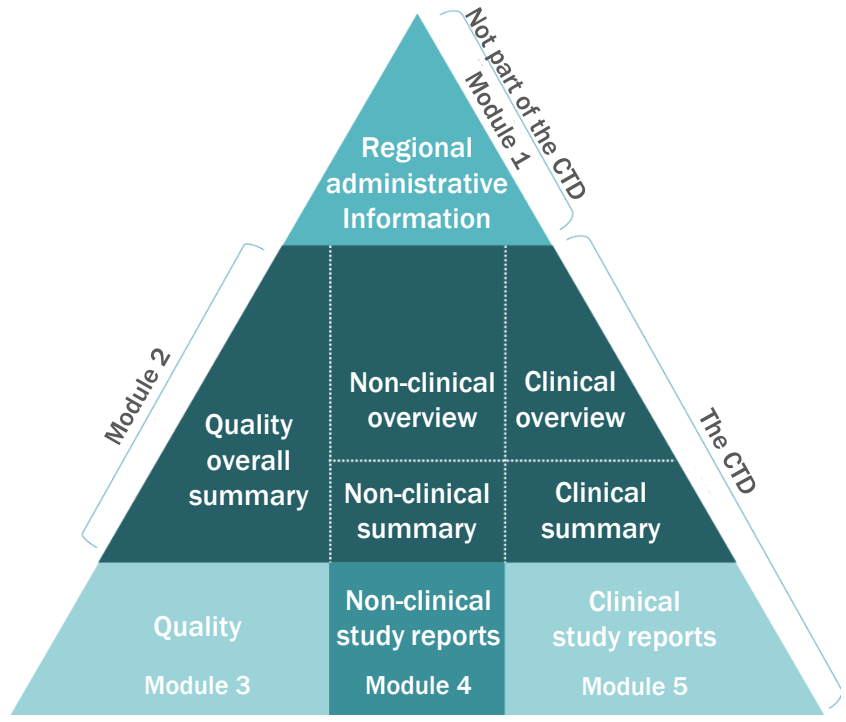
제품정보파일
PIF (Product Information File)

1. 제품 기술서 / Product Descriptions
2. 안전성 보고서 / Product Safety Report
3. 품질관리시스템 준수 / GMP or ISO Certificate
4. 효능·효과 입증 / Prove of Claim
5. 동물시험 결과(필요 시) / Animal Test (If necessary)

품질관리시스템 문서
GMP DOCUMENTATION

- Product Standard
- Manufacturing management standards
- Manufacturing management procedure
- Quality control manual

국제 표준화 문서
CTD (The Common Technical Document)



의료기기 기술문서
STED (Summary of Technical Documentation)

- Device description and specification, including variants and accessories
- Information supplied by the manufacturer
- Design and manufacturing information
- General safety and performance requirements
- Risk analysis and risk management
- Labelling
- Essential principles checklist
- Product verification & validation
- Declaration of Conformity

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GLOBAL Standard Certificate Consulting

K-GMP will give you a quick and accurate advice on Global standard regulation and certifying

할랄, 유기농과 같은 국제 인증기관은 각 국가마다 설립되어 있습니다. 한국지엠피는 주요 수출국가를 모두 포괄하여 교차인증이 가능한 인증심사를 준비함으로써 국가마다 상이한 규제에 효율적으로 대응할 수 있도록 자문서비스를 제공합니다.

Global standard bodies such as Halal, Organic are established in each country. K-GMP provides consulting to efficiently respond to regulations by each country by preparing certification audits of institutions that can cross-certify all major exporting countries.

할랄 인증 / HALAL

- 제조공정도 및 제조시설 점검 / **Manufacturing procedure and Facility audit**
- 원재료 분석 / **Ingredients analysis (accepted by HALAL regulation)**
- 할랄 표준문서 및 서류 안내 / **Documents required for HALAL regulation**
- 현장 심사 대응 / **Audit assistant**

유기농 인증 / ORGANIC

- 비유전자변형 / **Non-GMO**
- 100% 유기농 / **100% Organic**
- 유기농 / **Organic**
- 유기농으로 만듦 / **Made with organic ingredients**

※유기농: 원료로 사용되는 제품을 재배할 때 화학비료와 농약을 사용하지 않았으며, 원료가 유전자변형 종자가 아니어야 함
※Organic: No chemical fertilizers or pesticides were used to grow the product used as raw material, and the raw material must not be genetically modified seeds.

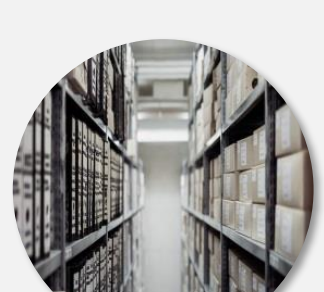
기타 인증 / OTHER CERTIFICATE

- DERMA TEST
- EVE-VEGAN
- GLUTEN-FREE
- EWG
- NON TESTED ON ANIMAL

K-GMP SERVICE

Country and related regulation analysis

Regulatory compliance and system



Documentation

Audit assistant

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