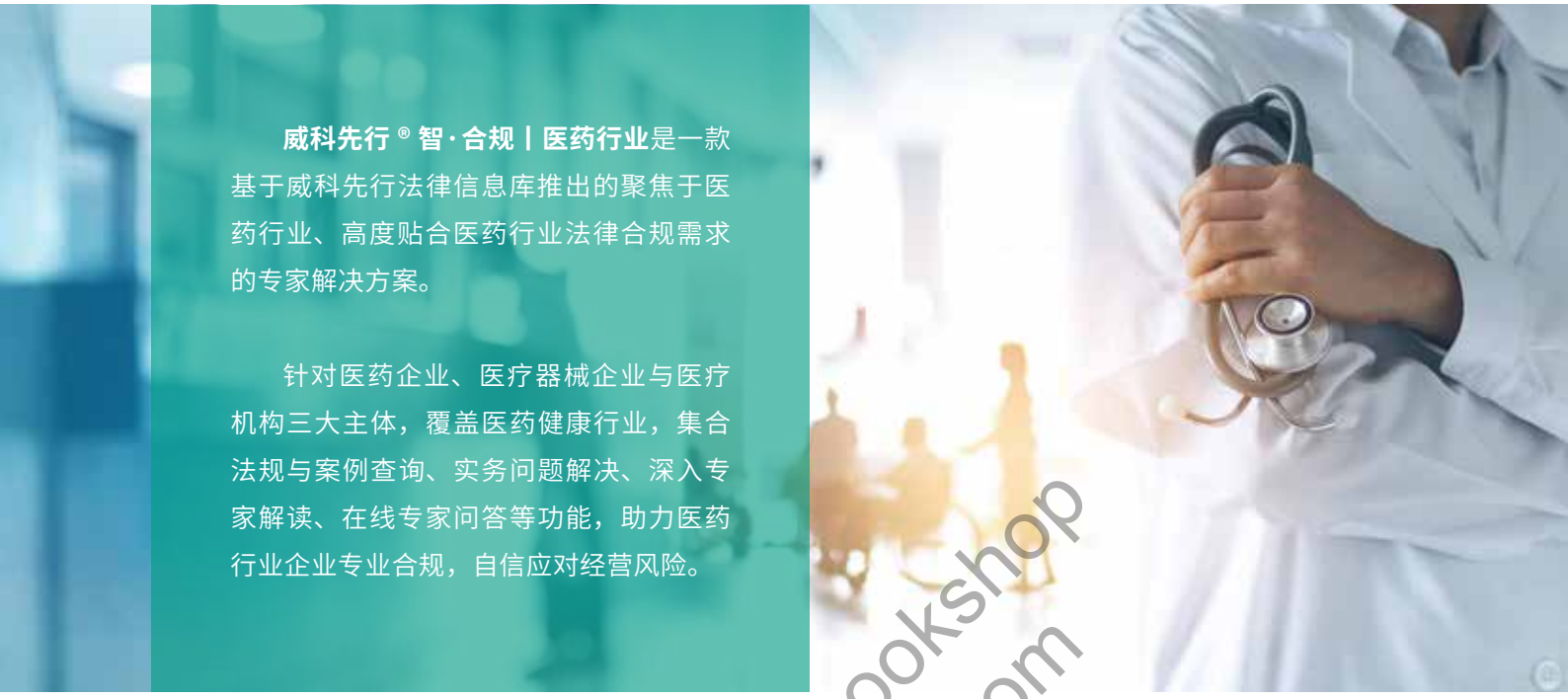
威科 Wolters Kluwer

威科先行
智·合规丨医药行业



威科先行 ® 智·合规丨医药行业是一款基于威科先行法律信息库推出的聚焦于医药行业、高度贴合医药行业法律合规需求的专家解决方案。

针对医药企业、医疗器械企业与医疗机构三大主体，覆盖医药健康行业，集合法规与案例查询、实务问题解决、深入专家解读、在线专家问答等功能，助力医药行业企业专业合规，自信应对经营风险。

医药行业一站式合规解决方案

行业聚焦，全新界面，体验更流畅更优质

针对医药行业不同企业类型提供精准信息，更深入更高效

• 企业入口

医药企业　　医疗器械企业　　医疗机构

覆盖企业生命全流程的信息指引，更清晰更完整

涵盖许可准入、合规管理、投资经营各发展阶段和方向的合规需求，更前沿更实操

• 业务实践指引

许可准入	人类遗传资源合规	监管法规汇总	第三方合规管理
合规管理	医疗机构合规清单	反商业贿赂合规 HOT	广告合规
投资经营	反垄断立法执法	医药行业小威课堂	医药出海

权威医药行业法律合规专家保驾护航，更专业更自信


黄建雯


傅长煜


周 磊


沈 涛

优势功能与内容，您的医药行业合规专家

包含海量信息，全方位功能与栏目强强联合

囊括 15 项优势栏目功能，更智能更丰富：

- 海量法规精中选精、及时更新、高效检索、智能关联、批量下载；
- 飞行检查文书、行政处罚、裁判文书、典型案例等多种官方案例资源，助您掌握监管口径与动向；
- 集合业内专家及时、深入解读的专业文章，成体系剖析实务问题的专题聚焦，大体量高价值的实务指南，层层递进为您的实务操作保驾护航；
- 更有多种形式的工具助手（智能图表、智能决策、内训助手）助力您的效率提升；
- 实时更新的行业动态，帮您把握前沿态势、洞悉行业发展。

深耕重点问题与解决方案，关注您最关注的领域，解决您最需解决的问题

■ **详细梳理、精华汇总医药企业、医疗器械企业、医疗机构各业务流程重点合规问题，并对各环节下热点问题提供深度解读，十大精华汇总助力合规全流程闭环管控**

（医药企业研发环节精华汇总）

（医药企业经营环节精华汇总）

- 反商业贿赂、第三方管理、广告合规实务助手涵盖实操报告、内训模板、热点解读等多种高价值资源，三大实务助手，助力专项合规一站到底

（医药行业反商业贿赂合规实务助手）

（第三方管理合规实务助手）

（医药行业广告合规实务助手）

实操报告兼具体系化与实操性，解决实务痛点，提供合规指引

热点专题	·Q & A	安杰世泽医药行业实务问答专栏 ·反垄断十五年案例研究系列报告之医疗篇 ·中国人类遗传资源合规操作流程指引（含工具） ·药品专利链接制度研究 ·医疗机构合规必备清单：109 个业务合规要点 ·医护人员执业合规全解析 ·生命健康与医疗法律月报
实务报告	·医药行业合规与投融资实务问答 ·医药行业全生命流程实务问答 ·中国反商业贿赂执法报告 ·医药医疗行业合规政策热点及典型案例回顾手册 ·互联网医疗与药械网络销售合规指引 ·药品、医疗器械企业营销推广业务模式合规指引
内训资料	· 医药行业反垄断立法、执法观察 · 医药行业税务风险与检查应对 · 医药行业反腐败近期执法要点 · 药链和 PTE 制度下 License-out 项目中的专利要点 · 医药行业广告合规风险 · 医药行业 ESG 供应链和 ESG 披露的法律问题介绍 · 医疗企业出海的数据合规操作路径 · 生命科学及医疗企业出海多样模式分享 · 医疗器械企业出海的法律热点问题分析 · 企业全球化布局与境外上市架构搭建

独特的智能风险筛查工具，以清晰易用的图表形式梳理展现，汇聚多维度相关信息，便捷、高效

医药行业行政处罚风险提示与防范解析智能图表

内容介绍：

本智能图表提供医药行业行政处罚事项的梳理内容，针对医药企业 (含 MAH、CRO、CMO、CDMO、CSO)、医疗器械企业 (含 MAH、CRO、CMO、CDMO、CSO) 及医疗机构三类主体，分别提示风险行为、梳理处罚依据、处罚内容及参考案例，并邀请专业律师撰写防范解析，助力您实现高效合规。

药品监督管理局行政许可事项清单智能图表

内容介绍：

本智能图表提供药品监督管理局行政许可事项的梳理内容，涵盖药品、医疗器械、医疗机构 (含从业人员) 主题下的许可事项，覆盖重点地域级别，提供行政许可事项的信息及办事指南，用户可根据查询需要，定位主题和目标地域 / 级别后选择事项类别快速查找。

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Smart Compliance for Pharmaceutical Industry

Smart Compliance for Pharmaceutical Industry is launched by Wolters Kluwer Legal Information Database to provide targeted compliance solutions for the pharmaceutical industry.

The product aims to serve pharmaceutical companies, medical device makers and medical institutions, and offers functions like access to laws, regulations and cases, addressing legal practical problems, providing expert explanations and online Q&As, to help companies do business in compliance with related regulations and deal with operational risks.

One-stop compliance solution for the pharmaceutical industry

Industry focus, all-new interface, and better experience

Provide targeted information according to different types of companies in the pharmaceutical industry, information service is more profound and efficient.

- **Enterprise portal**

Pharmaceutical enterprises

Medical device enterprises

Medical institutions

Cover more clear and integral information guidelines in the whole life of an enterprise

Cover compliance requirements on licensing & access, compliance management and at different development stages and directions of business operation and investment

- **Business practice guide**

Licensing & access	Marketing compliance guide	Summary of regulatory rules	Third party compliance management
Compliance management	Text of compliance rules	Anti-commercial bribery compliance	Advertising compliance
Investment & operation	Bio-security	Marketing license holder	Medical data compliance

With instructions from our legal team with expertise in services to the pharmaceutical industry, you can deal with compliance issues more professionally and confidently


Huang Jianwen


Fu Changyu


Zhou Lei


Shen Tao

All-round functions and resourceful content, your adviser in pharmaceutical business compliance

Abundant information, all-round functions and columns

15 columns and functions offer smart services and resourceful content:

- Select useful information and quickly search information you need, timely update, smart link, bulk download;
- Unannounced inspection letters, letters of administrative punishment, ruling papers, typical cases and other official documents are provided to help you grasp regulatory criteria and trends;
- We collect profound and professional articles from industry experts to make systematic analysis of practical issues and provide valuable practice guide;
- We provide various tools (smart diagrams, smart decision-making and internal training assistant) to help you improve work efficiency;
- Our up-to-date industry news can help you grasp the development trend of the industry.

Our solutions target your biggest concerns and address your most-urgent problems

- **Summarize key compliance issues in the business processes of pharmaceutical enterprises, medical device enterprises and medical institutions, make in-depth discussions of hot issues and facilitate sound closed-loop compliance management.**

(Summary of major compliance practices in the phase of research & development at pharmaceutical enterprises)

(Summary of major compliance practices in the phase of business operation at pharmaceutical enterprises)

- Our compliance practice assistants for anti-commercial bribery, third party management and advertising include some valuable resources like practice report, template report on internal training and hot issue discussion, to provide one-stop compliance solutions.

(Compliance practice assistant for anti-commercial bribery in the pharmaceutical industry)

(Compliance practice assistant for third party management)

(Compliance practice assistant for advertising in the pharmaceutical industry)

The practice report can address your pain points and offer compliance guidelines

Hot topics	· Panoramic interpretation: anti-corruption action in the pharmaceutical industry ——Correcting improper practices in the field of pharmaceutical purchasing and marketing and medical services · Regulatory guidelines: Summary of regulatory regulations in the field of medicine and healthcare · Directions for websites related to medical supervision · Full analysis of medical professionals' practice compliance · Guidelines for special approval of medicines and devices ——A detailed explanation of the system for accelerating medicine listing registration and medical device innovation review · Practice manual for marketing authorization holder system · Practice guide on legal risk control for stem cell enterprises · 20 Q&AS to pharmaceutical R&D compliance risks, dispute resolution and rights protection · Legal and compliance guidelines for medicine donation in China and abroad · Monthly express on health and pharmaceutical
Practice reports	· 2023 Pan health industry integrity and compliance cases and practice manual · Review report on hot topics and typical cases of compliance policies in pharmaceutical and healthcare industry 2022-2023 · Compliance guidelines for online medical and pharmaceutical equipment sales · New M&A and compliance management practice manual for medical institutions · Compliance guidelines for marketing and promotion business models of pharmaceutical and medical device companies · China anti-commercial bribery law enforcement report
Internal training materials	· Anti-bribery trends in the pharmaceutical industry, compliance points and cooperation with government investigation suggestions · Pharmaceutical anti-corruption and enterprise compliance risk prevention and control · Key areas of anti-monopoly risk prevention in pharmaceutical industry · Latest progress and hot topics of cross-border data transfer in pharmaceutical industry · A-share comprehensive registration system and CSRC's new regulations on overseas listing filing · Common risks and negotiation strategies of life science technology (licensing in/out) transactions · Focus of Internet medical supervision and compliance guidelines · Key points of compliance on human genetic resources for pharmaceutical enterprises · Key points of compliance on product distribution and promotion of pharmaceutical companies

Our smart risk screening tool can present diagrams in an easy and straightforward manner to display multidimensional information and make your compliance work more convenient and efficient

Smart diagrams on risk warning and prevention of administrative punishment in the pharmaceutical industry

Content introduction:

The smart diagrams can remind pharmaceutical enterprises (Including MAH, CRO, CMO, CDMO and CSO), medical device enterprises (Including MAH, CRO, CMO, CDMO and CSO) and medical institutions of their risk behaviors, punishment reasons, punishment details and reference cases. We also invite professional lawyers to explain how to avoid administrative punishments and help you meet compliance requirements.

Smart diagrams on a list of administrative licensing matters to be approved by the drug administration

Content introduction:

The smart diagrams cover administrative licensing matters related to drugs, medical devices and medical institutions (Including medical personnel), and provide information about how to handle these administrative licensing matters at key jurisdictions. Users can pinpoint theme and target jurisdiction to select a type of administrative licensing matter and find related information.