

LIFE SCIENCES AND HEALTHCARE EXPERIENCES OF GLO

Beijing | Shanghai | Shenzhen | Chengdu 2023

中国首家律师事务所
The First Chinese Law Firm

www.glo.com.cn

About Global Law Office

The history of Global Law Office (hereinafter the "GLO") dates back to the establishment of China's Legal Consultant Office of the Council for the Promotion of International Trade (hereinafter the "CCPIT") in 1979. After years of persistent endeavours and development, we have become one of the largest and leading Chinese law firms.

We value the principles of simplicity, integrity and positivity. As a client-centered firm, we constantly improve our service and communications qualities, focusing on efficient and creative legal solutions for our clients.

Since its inception, GLO has been and remains committed to the mission of "serving domestic and foreign clients with a globalized vision, globalized team and globalized quality". This has allowed us to always maintain a leading position in the industry in the midst of an ever-changing global economic environment.

All of our lawyers graduated from top law schools at home and abroad, most of whom hold advanced qualifications such as LL.M or above. Some of our partners are also qualified and have practiced law in the United States, the United Kingdom, Australia, Switzerland, Singapore, New Zealand, Hong Kong and other regions. Our lawyers have outstanding and diverse practice backgrounds, many of whom have worked in the courts, regulatory bodies top domestic and international law firms or industry leading corporations and institutions.

With profound legal knowledge, extensive practice experience, high professional dedication and a strong sense of professional ethics, we have proved our values and earned the trust of both domestic and foreign clients. We are highly recommended as a leading PRC law firm being recognized as such by both international and domestic legal ranking bodies and directories (Chambers and Partners, The Legal 500 and Asian Legal Business, etc) and media for consecutive years.

We provide comprehensive one-stop legal services for domestic and foreign clients from various sectors and industries and continue to help domestic and foreign clients achieve enduring and long-term success via our unique advantages.



The First Chinese Law Firm
600+ Lawyers



BEIJING



SHANGHAI



SHENZHEN



CHENGDU

About China Life Sciences & Healthcare Law (CLHL)

Life Science & Healthcare

We have extensive experience in Life Sciences & Healthcare (L&H) practice, which allows us to take into account both the business and legal needs for our clients. We leverage the perfect combination of characteristics of L&H sector and our professional expertise to provide efficient and feasible solutions to our clients. We always adhere to the philosophy and principles that emphasize both industry background and legal knowledge, legal compliance and commercial feasibility.

We deeply understand the relevant laws and regulations of L&H sector in China, as well as the gradually complexity of the local operation environment.

We can provide clients with comprehensive legal services related to L&H, including drug research and development (R&D), clinical research organizations (CRO), pharmaceuticals, life sciences, animal medicine, biopharmaceutical, medical devices, supply producers and distributors, hospitals and other medical service providers and various investment funds in the L&H sector. Our L&H team has maintained the leading position in the industry, especially for the compliance related matters.

Our services mainly include:

- Compliance and regulatory
- Structuring industry-specific transactions and contractual arrangements
- Realization of pipeline and geographic expansions
- Capital raising and project financing, mergers and acquisitions, reorganizations,
- IP protection
- Licensing and distribution arrangements
- Dispute settlement for adverse effects in clinical trials medical treatment

First & Fully Dedicated

As the earliest L&H team in China, we are committed to providing customers with “one-stop” service to help customers in processing of M&A, investment and funding, license in and out, daily operation, IP protection, and advice on compliance including internal and government investigations as well as anti-bribery matters and dispute settlement.



Wide Coverage & Best Think Tank

As recommended as the “Industrial Pioneer” & “Best Think Tank” in L&H, our client base widely covers each track from fast-growing start-ups to MNCs and listed cooperates, also including Pes, governmental institutions and associations, serving almost each sector of L&H (pharmaceuticals, biotech, medical device to medical services).

Pioneer & Break-through

Under a changing regulatory environment, our team has perfect combination of international experiences and local knowhow to support various innovation or pilot projects, including digital healthcare, MAH/cMAH trial case, etc.



Benchmark Practice

We deeply participate in the formulation of local code of conduct and benchmark policies/rules. We also have close cooperation with associations, including CPIA, RDPAC, ACCP and so on.

Chambers
AND PARTNERS

Band 1 Law Firm in Healthcare
《Chambers and Partners》2013-2023



Top-tier Law Firm in Healthcare and Life Sciences
《The Legal 500》2018-2023

**ASIAN LEGAL
BUSINESS**

China Law Awards Healthcare Law Firm of the Year
《Asia Law Business》2018-2020&2022-2023

asialaw
PROFILES

Recommended Law Firm in Pharmaceuticals and life sciences
《Asialaw Profiles》2019-2022



Top-tier Law Firm in Healthcare & Life Sciences
《LegalBand》2015-2016 & 2018-2022



Healthcare PRC Law Firm of the Year for several times

《China Business Law Journal》 2016 & 2018-2021



Healthcare PRC Law Firm of the Year for several times

《China Law & Practice》 2013-2016 & 2018 & 2020



Band 1 Law Firm in Healthcare

《Dawkins》 2022



Licensing & Franchising Firm of the Year

《Asia IP》 2022



Top-tier Law Firm in Copyright/Trademark

《Asian Legal Business》 2022

“Global Law Office is a full-service powerhouse firm with a notable practice that offers longstanding experience in the healthcare sector, working with high-profile domestic and international pharmaceutical corporates and investment funds. Widely recognised for its expertise assisting clients in the pharmaceutical and medical arenas on M&A, joint ventures, funding, licensing and regulatory matters. Additionally advises on capital raising and IP matters. Well placed to handle internal and government investigations as well as anti-bribery matters in the health sector. Demonstrates wider strengths in areas including dispute settlement and compliance programmes. Also contributes to research projects and advises on legislative procedures relating to healthcare regulations.”

“They can provide solutions that we appreciate very much,” lauds a client, who further says: “They are very practical.”

----Chambers and Partners Asia-Pacific 2022

CHAMBERS
AND PARTNERS



**“INDUSTRY PIONEER,
BEST THINK TANK.”**
——**LEGALBAND**

Awards & Recognition

“Global is active on leading deals in healthcare and life sciences. They covers all aspects of the pharmaceutical and health industry, including compliance advice and review, project investment and financing, mergers and acquisitions, intellectual property protection and so on. It is a well-deserved “leader” in this field.”

——LEGALBAND



The team understands the business model and business practices of the life science industry and is experienced in supporting licensing and M&A transactions. Equipped with lawyers of different levels, the billing method is flexible.

——Legal 500



GLO is very familiar with the life sciences industry and always provides practical solutions.

——Asialaw Profiles



PRACTICE

General Corporate | Compliance & Risk Control

Alan Zhou is the head of Life Sciences & Healthcare (L&H) practice of Global Law Office. He has been recognized as a pioneer in providing outstanding legal and consulting services in the L&H practice. He has over 20 years of sophisticated experience working with multinationals, Chinese state-owned and large enterprises, and private equity/venture capital funds in the L&H area.

Mr. Zhou has been invited by local authorities and industry associations as a trusted advisor and legal professional to participate in the development of industry standards and legislative process, including the formulation of Healthcare Industry Compliance Guidelines, the formulation of Corporate Compliance Officer Professional Skill Standards, the formulation of pharmaceutical sales representative management guidelines, as well as developing emerging industries such as digital health and artificial intelligence in healthcare.

Mr. Zhou has been recognized with multiple awards and nominations for his work in the practice by top legal rankings. Meanwhile, with deep understanding of China's L&H industry, Mr. Zhou has been publishing academic articles and journals to support the development of China's L&H industry.

ASSOCIATION TITLES & CERTIFICATIONS

CEIBS Alumni Healthcare Association (CAHA) *Executive Manager / Secretary General Of Medical Association Committee*

China Healthcare Business Development (CHBD) *Vice President*

CCPIT *Expert Of National Cooperates Compliance Committee*

CPIA *Vice Chairman of the Compliance Committee*

ACCP *Vice Chairman*

CHIIPA *Chief Supervisor and Chairman of the Committee of Industry Experts*

INDUSTRY

Life-Sciences & Healthcare



Alan Zhou

Head of Life Sciences & Healthcare Practice

CONTACT

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EDUCATIONAL BACKGROUND

EMBA CEIBS

LL.B Shanghai International Studies University



Cross-border License Deal



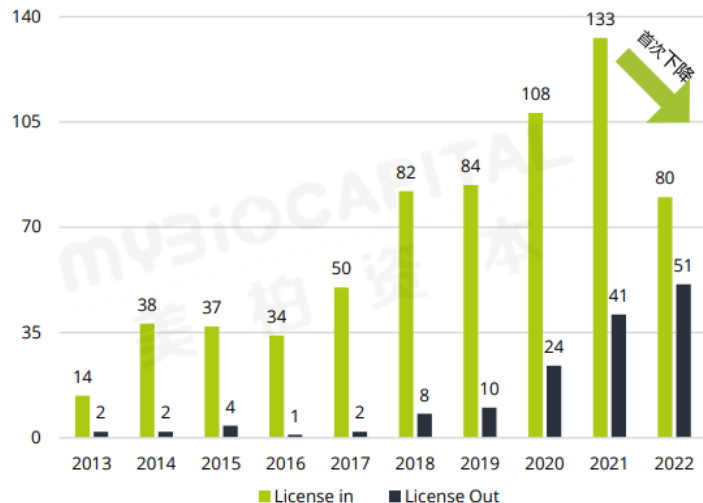
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Number of Cross-border License Deals in 2022:

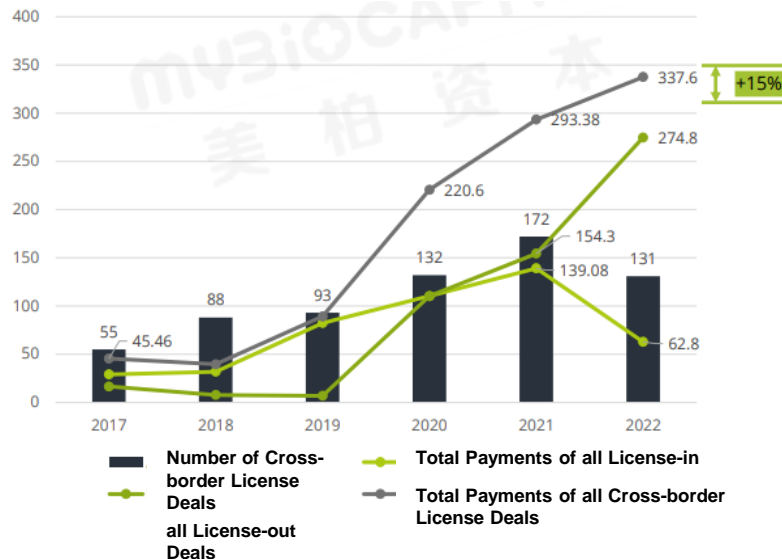
- A large drop in the number of cross-border license-in deals
- A steady increase in the number of cross-border license-out deals
- A 15% increase in the total payments of all cross-border license deals

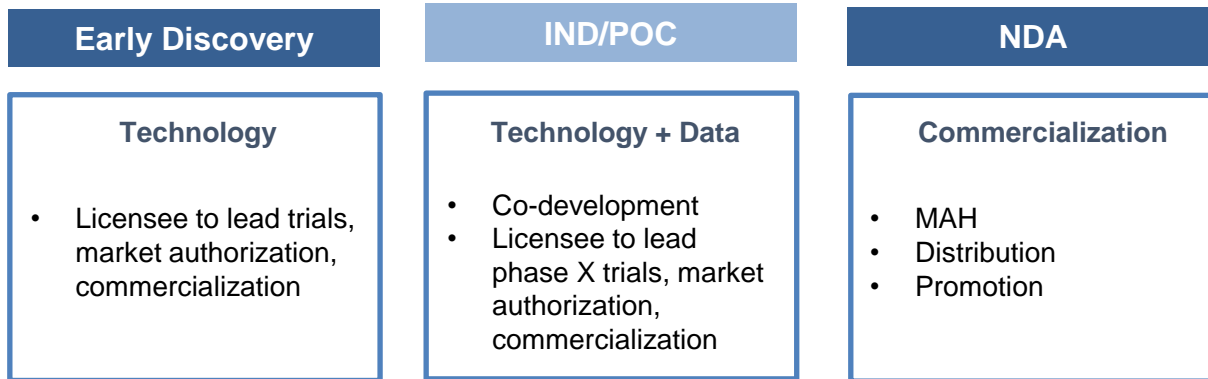
Number of Cross-border License Deals in the last 10 years



*Source: MyBioCapital (美柏资本)

Total Payments of all Cross-border License Deals





1. Local regulatory – trials/registration
2. Negative list for foreign investment
3. IPO plan
4. Export control
5. Manufacturing plan
6. Tax planning

Deal structure/contracting entity

Part I New Perspectives on Compliance Trend in Healthcare Industry

Legal Environment and Enforcement Trends in the Pharmaceutical Industry

Industry Policy Environment

- Socially-Run Medical Services
- Internet Healthcare
- Promote Hierarchical Medical System
- DRGs Payment Pilot

Drug Administration Law Revision

Priority Approval for New Drugs; Joining the ICH

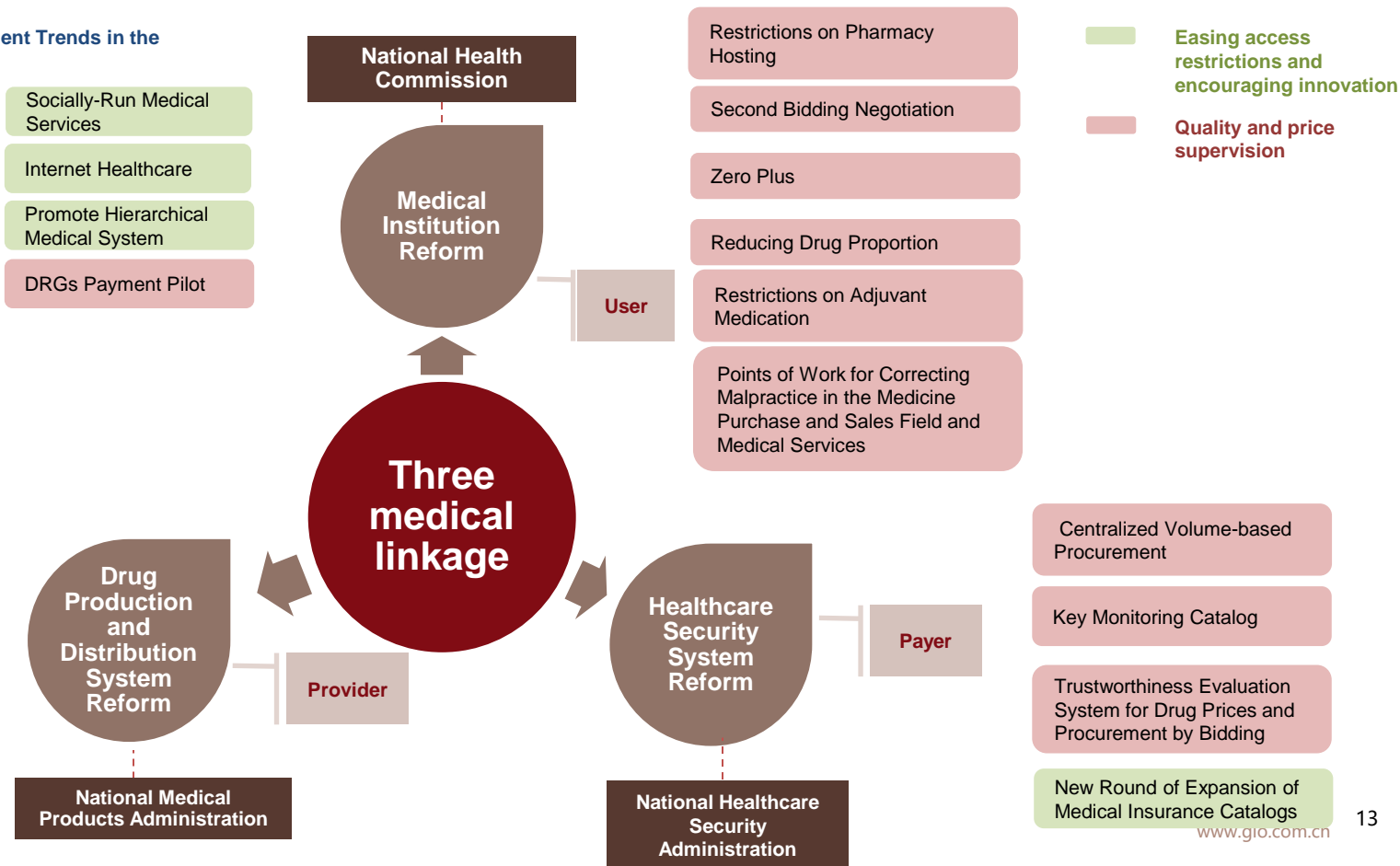
Listing Access; Generic Drug Consistency Evaluation; MAH; Clinical Data Verification;

Production; GMP; Overseas Inspection

Circulation; Two-ticket System

Flight Inspection

Pharmaceutical Representative Filing System



Self-evaluation of IP FTO Risk

- Degree of representation and warranty
- Scope of Responsibility Undertaken

Local Regulatory Issues

- Necessity to conduct clinical trials
- Local MAH holder
- Special requirements for CMO, such as halal certification in Indonesia

Payment Ability

- Due diligence on the collaboration company

DD on technology

LDD: ownership check

- Emdevelopemployee invention;
- Co-ent;
- 3rd party rights.

Stability: grantable or not; invalid

FTO: infringes 3rd party rights

Contract controlling point

- Upfront payment/Milestone
- Adjustment
- Territory
- Ownership of improvement/development
- Grant-backs clause
- Co-owned
 - Leading party
 - Patent / trade secret
 - 3rd party infringer
 - No-challenge clause

Product/Data

- IND/POC stage
 - Data exchange/sharing
 - Local regulatory issues
 - GCP compliance
 - CRO/CDMO

Contract controlling point

- Title of POC/MAH
- Cost sharing
- JSC
- HGR management
- Data exchange/sharing (cybersecurity, PI)
- Export control

Commercialization

- NDA
 - Manufacturing (CMO)
 - Channel
 - Bidding restrictions
 - CSO

Contract controlling point

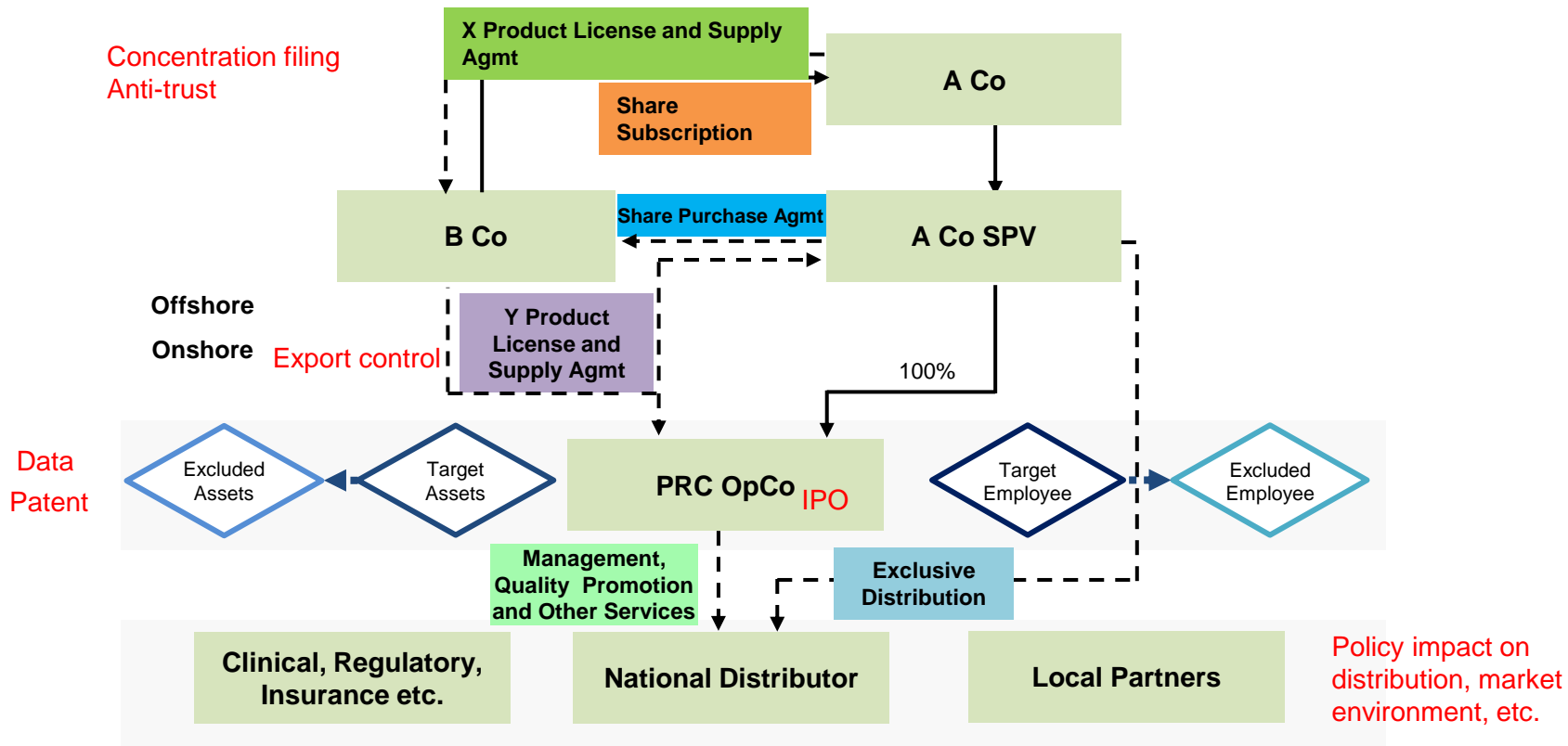
- Forecast and pricing
- Short of supply
- Inventory/Write off rate
- Anti-corruption
 - MR filing
 - Compliance KPI
- Anti-trust
 - Pricing
 - Territory
- Promotion/advertising
- Governmental investigation
- Audit

Adjustment

- Valid claim
- Volume-based procurement
- Generic version
- Bidding price drop
- Change of control
- Policy change

Contract controlling point

- Payment adjustment
- Right of re-negotiation
- Termination
 - Assignment
 - Free license
 - Inventory
 - Risk of policy change



We have a team of specialist lawyers in China Life Sciences & Healthcare Law able to support you globally, including the contacts below:



China Life Sciences & Healthcare
Law (CLHL)

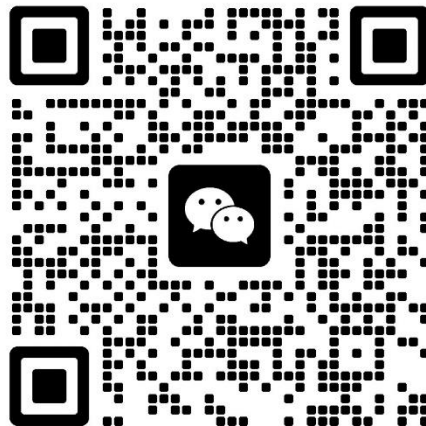
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or follow us on LinkedIn



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