

Quality and Innovation in the Clinical Label Supply Chain

Suzhou, China

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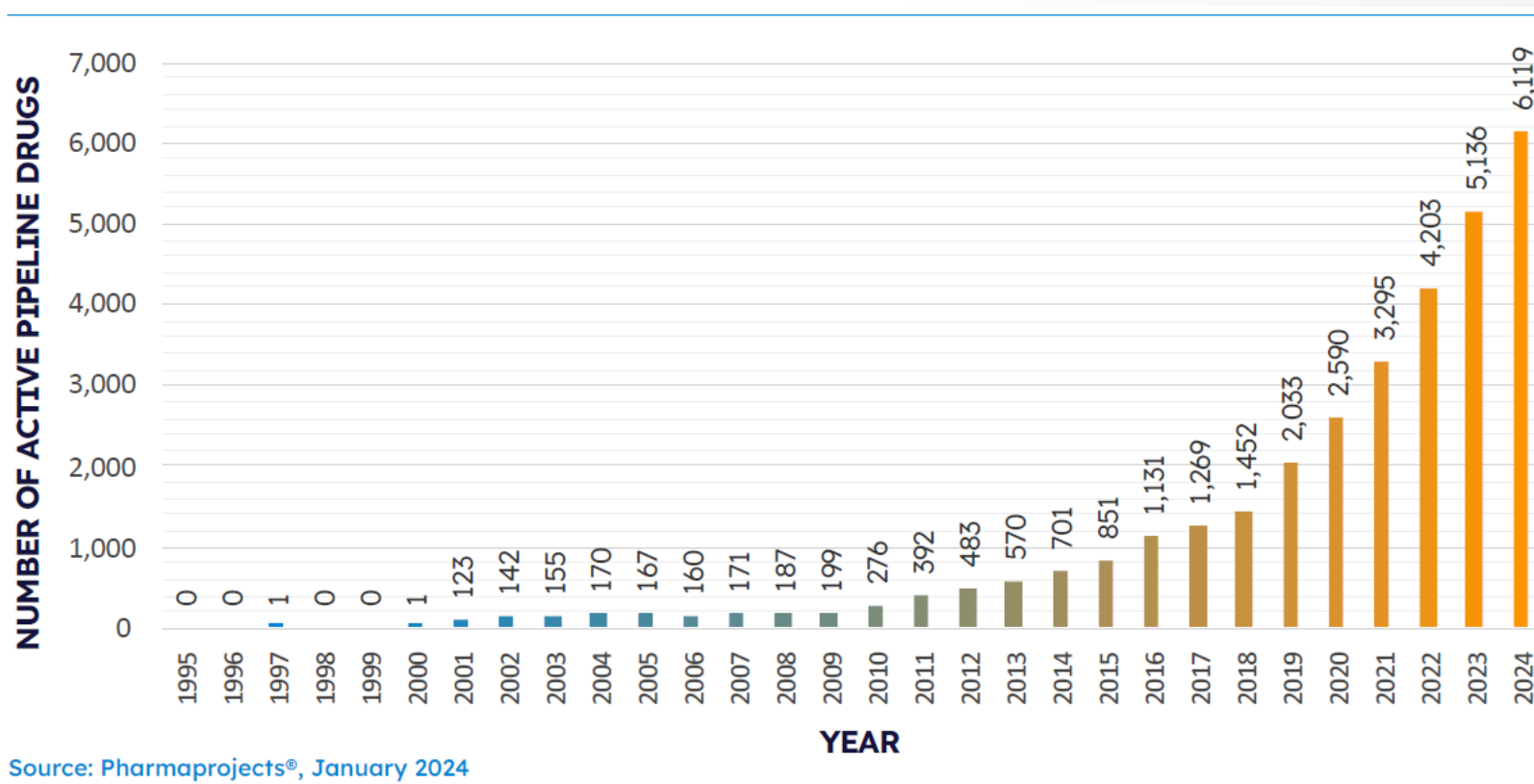
General Manager, Global Label Services

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 The world leader in serving science



China Pharma R&D pipeline size, 1995—2024



- China is currently responsible for developing 26.7% of globally active drugs, the second-largest developer of new drugs
- Total of 1,270 pharmaceutical companies headquartered in China, second only to the US.

Drivers of China Innovative Pharmaceuticals going abroad



China Market

- Policy-driven innovation gaining momentum
- Local innovation capabilities gradually maturing



Global Market

- Vast opportunities for innovative drugs
- High potential for premium pricing.

Labeling requires specialized expertise

Overcoming challenges to help you accelerate your clinical milestones

- **Equipment and expertise** – Clinical trial printing at scale requires capital equipment as well as specific industry experience
- **Strong quality processes required** – Quality systems and automation need to be in place that address all aspects of clinical labeling
- **Long cycle times can impede progress** – A lack of standard processes for translations and regulatory review can lead to excessive cycle times



Dedicated focus on
clinical labels



Patient-centric
solutions



Industry best
timelines



A global network of strategically located cGMP facilities

Ongoing investments to support growth and continuous improvement with first-class timelines



Industry-leading timelines*:

- 5 days standard, single-panel manufacture
- 5 days variable print manufacture
- 10 days bulk booklet manufacture

Labeling capabilities include:

- Translations
- Booklets and standard labels
- Bulk storage
- Program management support
- Label design
- Variable print and inspection

*Timeline starts from proof and links report approval

Industry leading clinical label manufacturing

Fully owned facilities strategically placed around the globe to accommodate local and regional needs



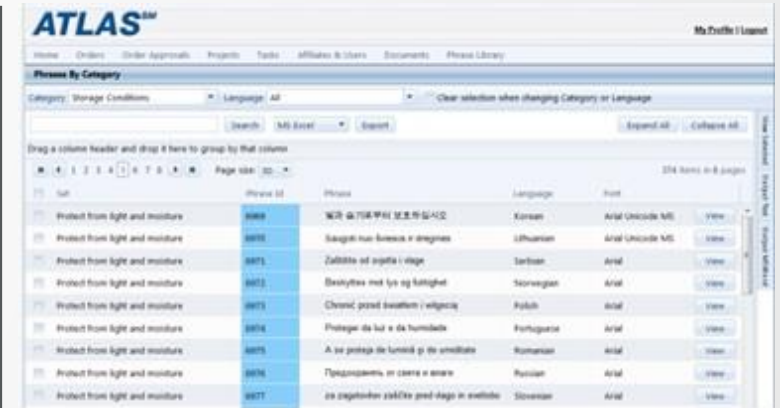
In-house design and manufacture Focused on clinical trials

- First-class cycle times in the industry and ability to expedite as needed
- Consultative project management
- Booklets and standard (single/multi-panel) labels
- Bulk label manufacturing and storage
- In house label design, translation and variable print
- R&D lab for material and construction testing



Quality oversight Quality driven automated processes

- Integrated cameras and IT systems resulting in right first-time, risk-controlled productions
- Qualified global network of facilities for digital labels
- 100% inspection of black text utilizing in line automated processes



Translation management services Industry leading translation services

- ATLASSM – reduces timelines by 50% or more
- Streamlines label processes from text translation through manufacturing
- Houses client specific phrase library and country regulatory requirements
- Reduces translation costs and overall label generation cycle times

Quality by Design: automated inspection of variable print

Integrated (in-line and in-process) cameras and IT systems ensure right first-time, risk-controlled label production processes

Inspection across many aspects of label manufacturing:

- 100% automatic inspection of black text
- Cosmetic inspection (ghosting, light text, print registration)
- Durable, fully laminated labels protect the label data/text

Automated inspection tools:

- Variable text inspection using optical character recognition
- Text verification tool (TVT software) compares client provided text to labeling team designed text
- Guardian scan verifies the printed label against text files



Case study: ATLAS reduces text translation timeline by 70%



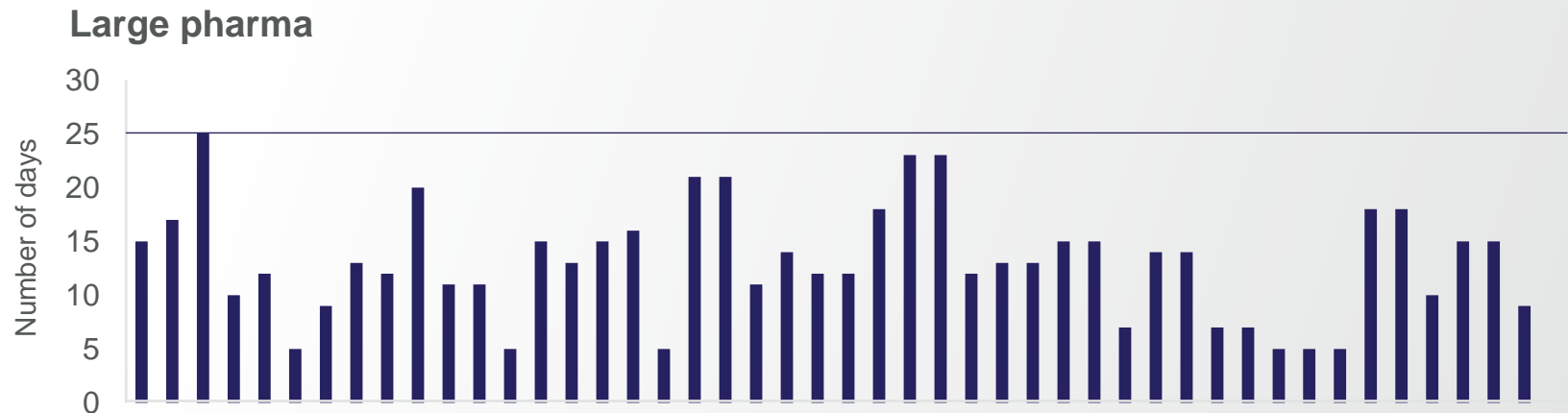
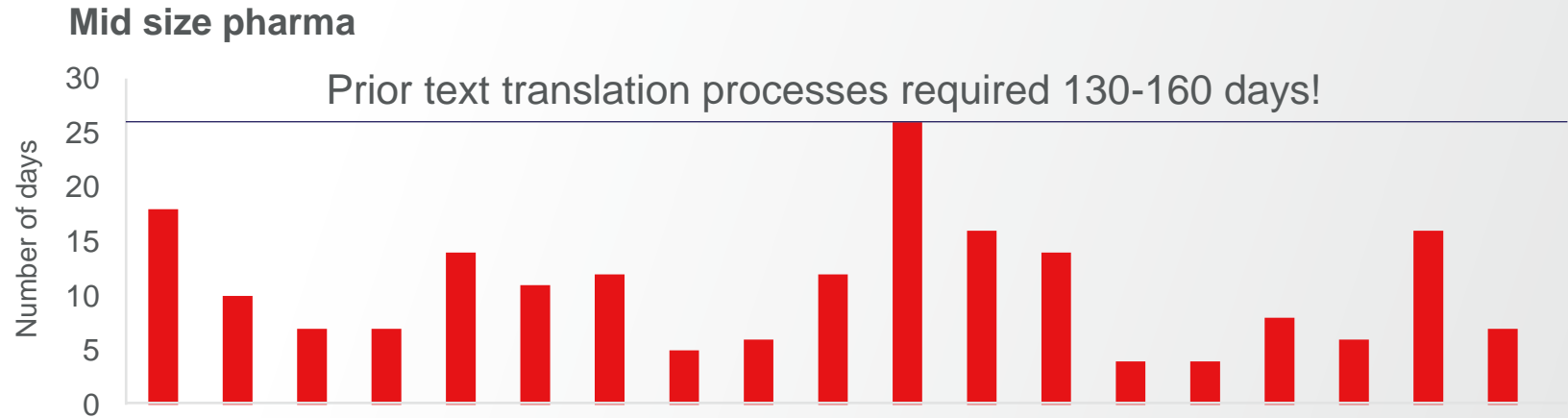
ATLAS changes the game for text translation – transforming months long processes into days

Previous processes tracked at ~130 to 160 days

ATLAS order placement, proofs created, proofs approved

Averaging over 70% reduction of text-generation timelines

Potential to shift study start-up by several weeks/months



Case study: Bulk printing to reduce cost and timelines

Strategy of bulk printing with variable print per study saves pharma client over **\$280k in one year**.

Goal



Support seven (7) different clinical trials for one customer under tight timelines and budget constraints.

Challenge



Label printing for multiple individual studies was leading to high label costs and long timelines.

Solution



Bulk print booklets



Store bulk labels for client free of charge



Variable print on stored bulk labels for individual clinical trials as needed throughout the year

Result

- Over **\$280k savings in one year**
- Label **timelines cut in half** (reduced from >2 weeks to <1 week)
- 65k labels printed
- 7 different clinical trials supported



Continued investments in global label network

Expanded clinical label solutions in the EU now include digital booklet label production



Open
Overall size

May 2024
2100 sqm)

- ➔ **Strategically located** Co-located with packaging facilities to streamline label and packaging project timelines for EMEA region
- ➔ **Purpose-built clinical label facility** 2100m² of digital booklet and clinical label manufacturing space, as well as on site design and project management provide end-to- end in house services
- ➔ **Network support** from integrated Thermo Fisher facilities provide supply chain assurance and additional capacity expansion capabilities
- ➔ **Exceptional expertise** In the unique requirements of clinical labels, supporting global design, translation and regulatory requirements

Suzhou clinical label production

Supporting clinical label production for APAC region



In-house capabilities	
Single, Multiple Panels, WAO, Booklet Variables	✓
Label design	✓
Project management	✓
Blank label manufacturing	✓



Opened
Oct 2024

Overall size
450 sq. m.

Clinical Label Services cycle times

Label Services Process

Customer submits order to Client Services



Translations and Regulatory Services

10-15 days



Label design

2-5 days



Customer approval

Label manufacturing

1-10 days



Variable Print and Randomization

1-5 days

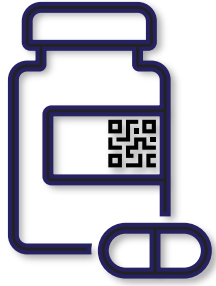
Timelines

Clinical Labels Global Network	Translation Management	Label Design	Single Panels <5 Days	Booklet <10 Days	Variable Print <5 Days
Bohemia, NY	●	●	●	●	●
Basel, Switzerland	●	●	●	●	●
Suzhou, China		●	●		●
Ahmedabad, India					●

Best-in-class cycle times and quality via investments & continuous process improvements

Focus on the future: Innovative clinical label solutions

Providing information and assurance at a patient's fingertips



Drug packaging labeled with QR code

Patient scans the code on the label

Patient accesses supplemental information

Information Supported

- Multi-language label text
- Videos
- Emergency information
- Patient inserts/handouts
- Other, non-regulated content

Benefits

- ✓ Improves patient safety and experience
- ✓ Supports investigative site/patient protocol compliance
- ✓ Access to late-stage changes/updates

Digital solution for delivering clinical trial information and content via a mobile web application

Labeling expertise to help you hit clinical milestones

Fully owned global facilities strategically located to accommodate local and regional needs

100+

languages supported

>50%

reduction in delivery cycle times in 2023

49M+

labels produced annually

90+

countries supported

30+

years experience in clinical trials



In-house design and manufacturing exclusively focused on clinical trials deliver accelerated cycle times



Lead times as low as 5 days for standard and single-panel labels, and 10 days for booklet labels*



Quality-driven **automated processes with integrated cameras and IT systems** ensure right-first-time, risk-controlled production



Industry-leading translation management services **streamline label processes and reduce translation timelines by 50% or more**

*Timeline starts from proof and links report approval

Thank you

