Lonza

Pharma & Biotech

on-time regulatory documentation

Our embedded Regulatory Affairs Services ensure authorities get the documentation they require in time to hit your next milestone.

Today timelines for drug development are getting shorter and shorter with 40% of approvals being expedited*. In order to keep up with the tempo and stay ahead of competition every link of the chain from research, drug substance/drug product development and manufacturing needs to be in-sync. Timely and proper documentation and communication with the appropriate regulatory authorities can make a difference.

Predictable approval timelines facilitated by regulatory experience and preparedness

With regulators steadily increasing their patient focus and safety considerations, it's vital to seek expert consultation and support in dealing with new and/or specific documentation requirements. Only through close collaboration with your CDMO partner will time lines be kept for a successful filing.

Hands-on practical experience from early development through the clinical programs to the approval of license application

To fulfil authorities' requirements for documentation our regulatory specialists serve as a critical link between your (clinical) research and our development services. Having supported more than 50 chemical MAA, NDA, DMF and ASMF's there is not much in regard to questions, challenges or problems that our regulatory affairs team has not encountered and solved over the past years.

With timelines nowadays being tight and challenging to achieve (e.g. accelerated regulatory pathway), the number of interfaces within a process may be decisive for a fast and smooth flow of data, documents and communication. As part of our CDMO organization, your dedicated regulatory affairs specialists are present at the drug substance and drug product manufacturing site ensuring exactly this continuous and unhindered exchange of information.

* Priority Review, Breakthrough Therapy, accelerated approval, Fast Track

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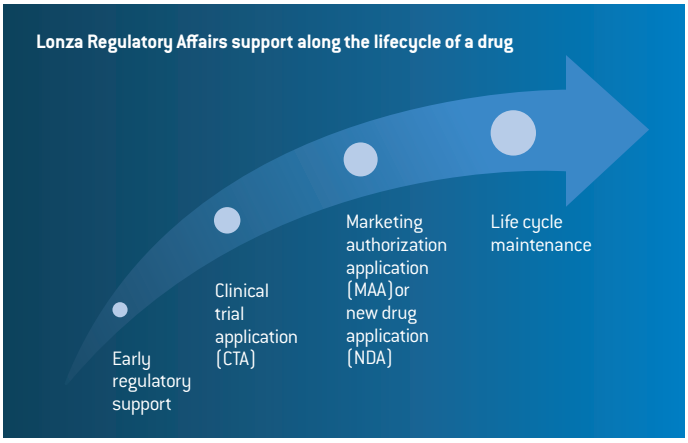

Reducing the time and cost impact for our customers

Regulatory and health authorities heavily scrutinize and challenge new drug developments and required documentation. This can be especially daunting to new and small biopharma companies. Our regulatory services are designed to support your needs during the clinical phases and registration application so that you do not have to hire additional regulatory resources or consultants.

With extensive experience in writing and facilitating responses to questions raised by health authorities – and a track record of successfully challenging their positions by applying sound scientific justifications – our regulatory team guides you through the entire process.

To serve as an effective partner, our teams always keeps pace with regulatory and health authorities' thinking in emerging therapies and new technologies. This systematic monitoring of regulatory trends and topics is critical in our ability to serve as your integrated development and manufacturing service partner.

Above all, we view regulatory authorities as your customer, and take a proactive approach in providing documentation so that risks are mitigated as early as possible, timelines are kept and successful outcomes achieved.

If you want to focus your efforts on the clinical development of the drug, as your CDMO partner, we will provide you with regulatory affairs services.

Why choose Lonza's Regulatory Affairs Services for your drug program

- **Integrated** – Project-dedicated Regulatory Affairs team based at each development and manufacturing site within the Lonza Pharma & Biotech network. **These regulatory specialists are integrated with the functional teams supporting your project to ensure appropriate documentation and proactive identification of potential regulatory hurdles.**
- **Engaged** – Present at all internal project meetings and fully informed of the development, tech transfer and development challenges involved and manufacturing campaign planned. **The Regulatory Affairs specialists assigned to your project are always directly available for discussions with you and your teams.**
- **Experienced** – Regulatory Affairs specialist team with broad backgrounds across QA, QC, product development and operations, as well as with regulatory and health authorities.
- **Proactive** – Responsible for incorporating all relevant regulatory considerations into the development and manufacturing program. **Assesses manufacturing change requests prior to approval and implementation for CMC documentation.**
- **Informed** – Global Intelligence network which follows regulatory legislation and guidance development worldwide. **We provide you with interpretations to make the qualified decisions.**

Contact us

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