COVID-19 SURVEY REPORT

BY: LACHMAN CONSULTANTS

April 2020

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COVID-19 SURVEY REPORT: SUMMARY

ABOUT THE SURVEY
LEGAL NOTICE

From March 31 through April 14, 2020, Lachman Consultant Services, Inc. (Lachman Consultants) conducted a voluntary survey of professionals working in the pharmaceutical, biotechnology, medical device and other sectors related to the greater life sciences industry. The purpose of the survey was to take a "pulse" of the overall organizational and industry impact of the COVID-19 pandemic. The survey was distributed through LinkedIn and by direct e-mail. The responses thereto have been reviewed and analyzed by Lachman Consultants and relevant observations are set forth herein. The information displayed herein is provided "as is". Lachman Consultants makes no representations or warranties of any kind, either express or implied, with respect to the contents and information presented, including as to its accuracy, completeness, or reliability nor to the suitability of the information contained herein to a particular circumstance. Lachman Consultants will not be liable for any damages of any kind arising from the survey or publication of its results or the use of the information contained herein, including, but not limited to direct, indirect, incidental, punitive, and/or consequential damages. All original content, as well as the compilation, collection, arrangement, and assembly of information provided on these slides, including, but not limited to the analysis and examination of information herein, are the exclusive property of Lachman Consultants protected under copyright and other intellectual property laws. These presentation slides may not be displayed, distributed, reproduced, modified, transmitted, used or reused, without the express written permission of Lachman Consultants.

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ORGANIZATIONAL OVERVIEW

By a wide margin, respondents described their organization as global (63.16%) pharmaceutical (78.95%), while almost half described their current position as quality and regulatory (49.12%) and current location in North America (70.18%).

COVID-19 IMPACT

Almost half those surveyed (47.37%) anticipated work stoppages due to the pandemic. One-third (31.58%) of respondents expected a return to normal operations within six months, while another third (33.33%) did not anticipate resuming normal operations for a year.

Upon resuming operations, main challenges included clinical trial delays (26.32%) and diversification of supply chain (35.09%), while almost all (89.47%) expressed concern in the integrity of their supply chain.

However, only slightly more than than one-third (35.09%) had experienced problems obtaining goods or raw materials to continue production.

Since the issuing of travel restrictions, inspections from outside the respondents' country or region have seen dramatic reduction in frequency (89.47%).

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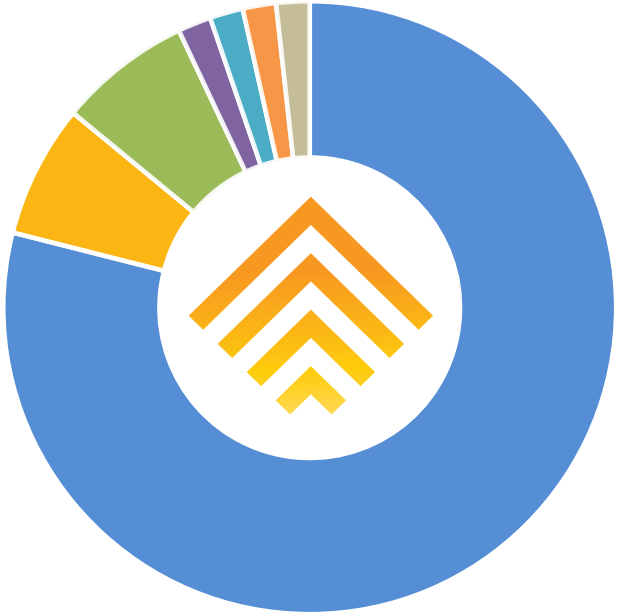
WHICH INDUSTRY BEST DESCRIBES YOUR ORGANIZATION?



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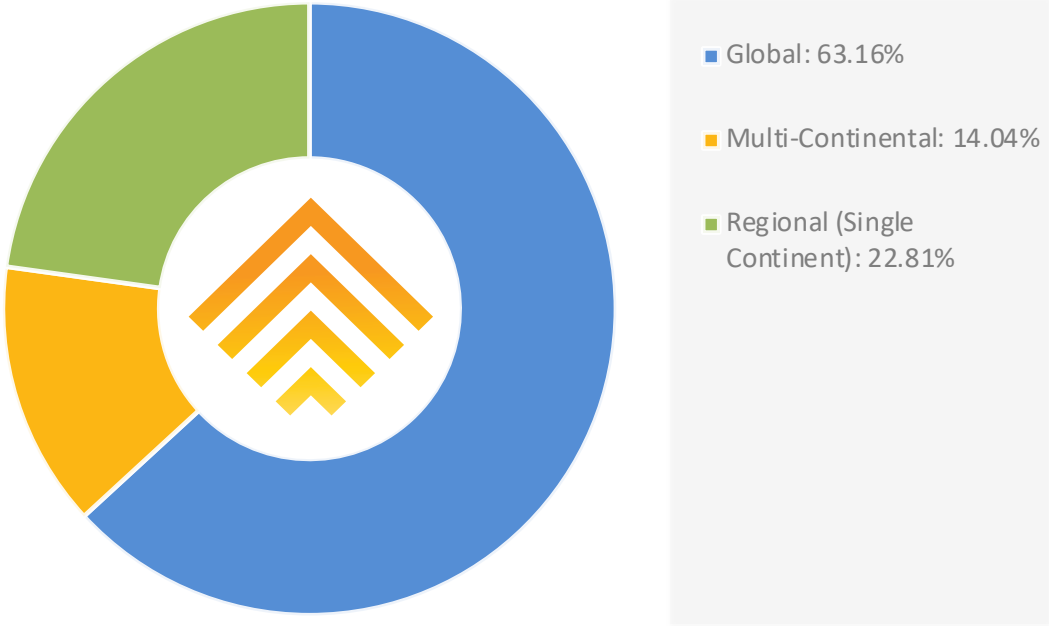
WHAT BEST CATEGORIZES THE "REACH" OF YOUR ORGANIZATION?



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WHICH CATEGORY BEST DESCRIBES YOUR CURRENT POSITION?

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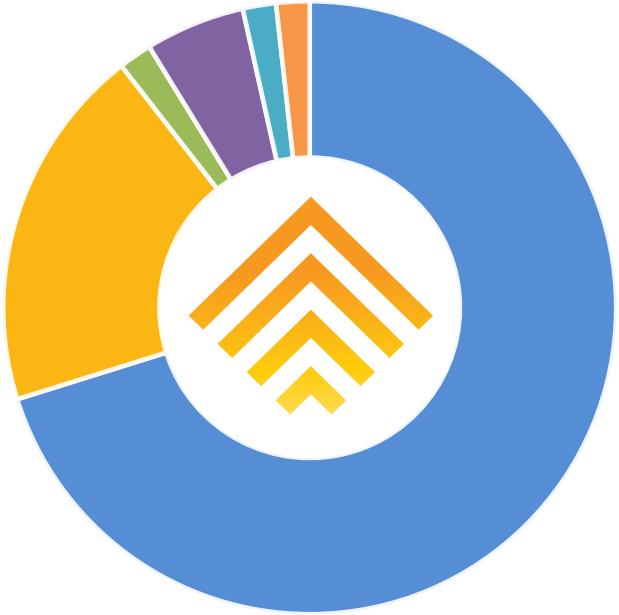
WHICH REGION BEST DESCRIBES YOUR GEOGRAPHIC LOCATION?



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IS YOUR COMPANY CURRENTLY EXPERIENCING OR ANTICIPATING WORK STOPPAGES DUE TO COVID-19?

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HOW WOULD YOU RATE YOUR CURRENT LEVEL OF CONCERN ABOUT THE INTEGRITY OF YOUR SUPPLY CHAIN?

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ARE YOU CURRENTLY HAVING DIFFICULTY OBTAINING GOODS OR RAW MATERIALS TO CONTINUE PRODUCTION?

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ARE YOUR LOCAL PHARMACEUTICAL INSPECTION AUTHORITIES CONTINUING TO PERFORM INSPECTIONS?

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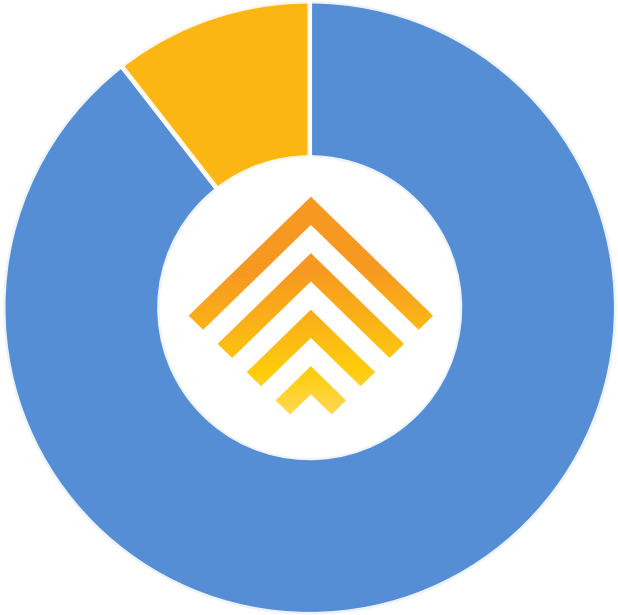
SINCE THE START OF TRAVEL RESTRICTIONS, HAVE YOU HAD ANY INSPECTIONS FROM REGULATORY AUTHORITIES OUTSIDE YOUR COUNTRY OR REGION?



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HAS YOUR COMPANY SHIFTED, OR WILL YOUR COMPANY SHIFT PRODUCTION TO MAKE DRUG PRODUCTS, MEDICAL EQUIPMENT, AND/OR DEVICES OR SUPPLIES THAT ARE NECESSARY IN THE FIGHT AGAINST THE THREAT OF COVID-19?

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HOW LONG DO YOU ANTICIPATE THIS CURRENT SITUATION TO IMPACT YOUR BUSINESS'S ABILITY TO RESUME NORMAL OPERATIONS?

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WHAT ARE THE POTENTIAL CHALLENGES YOU ANTICIPATE UPON RESUMING NORMAL OPERATIONS?

Experience. Excellence.

THE MOST EFFICIENT SERVICES.
THE MOST QUALIFIED PROFESSIONALS.

Since 1978, Lachman Consultants' multidisciplinary team of highly experienced FDA and industry experts has offered compliance, regulatory affairs, and technical services to clients around the world.

Lachman Consultants: Trusted Expertise, Valued Relationships

Senior Consultants.

Lachman's team has a solid knowledge base and wisdom that can only come from decades of industry experience.

Efficient Engagements.

The knowledge and experience of Lachman consultants help to ensure that desired outcomes are achieved quickly and with greater efficiency.

Integrated Expertise.

Lachman's three practice groups collaborate extensively, ensuring that problems entrusted to us are addressed from all possible angles.

Loyal Clients.

Lachman consistently delivers thoughtful, effective solutions, which is why clients repeatedly turn to us for help with their most challenging compliance and regulatory issues.

Lachman Consultants: Insight, Guidance, and Responsive Support

Advance confidently with our full suite of targeted, efficient, and effective solutions.

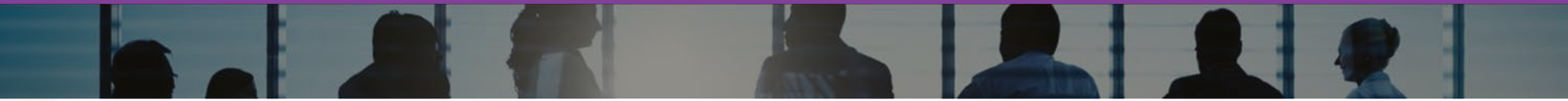
COMPLIANCE

- Wide range of mission-critical services to the regulated industry
- Sustainable compliance through optimal integration of scientific, technical, and regulatory principles
- Stay current with the ever-changing regulatory and technical environment

TRUST LACHMAN FOR:

- FDA 483 inspection response
- FDA Warning Letter response
- Meeting with the FDA to resolve disputes
- Implementing corrective and preventive action (CAPA) programs including development, execution, monitoring, and project management
- Providing assistance in “a third-party role under a consent decree”
- Specialized and effective auditing techniques

REGULATORY AFFAIRS



- Comprised of former senior-level FDA managers, FDA reviewers, and industry experts
- A stellar reputation for simple, workable solutions to regulatory problems or issues
- High-quality documents that move clients quickly to the desired outcome

TRUST LACHMAN FOR:

- Advice and guidance regarding US-FDA related regulatory issues
- Gap analysis of FDA-related applications
- Development of regulatory strategies for complex generics
- Providing lifecycle support through approval
- Supporting 505(b)(2) applications
- Compilation, submission and lifecycle management of FDA-related applications
- Supporting regulatory filing due diligence audits
- Integration of all aspects of the Regulatory Affairs disciplines following acquisitions

SCIENCE & TECHNOLOGY

- Effectively addresses issues with a thorough and balanced approach
- Intimate understanding of the complex scientific and technical challenges clients face
- Solutions are scientifically and/or technically accurate and actionable within clients' operations

TRUST LACHMAN FOR:

- Comprehensive quality control laboratory training and qualification courses/programs
- Specialized training and technical publications
- Specialized and effective auditing techniques
- Scientific support for the timely resolution of complicated scientific issues
- Scientific guidance to understand and resolve adverse FDA 483 observations and warning letters

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THANK YOU