



Regulatory Affairs During COVID-19

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A Look at Our Response to a Pandemic

Regulators across industries have recognized the significant impact that the spread of COVID-19 may have on the markets, organizations, and consumers. Concurrently, organizations are navigating new compliance challenges resulting from COVID-19. The Charles River Regulatory Affairs (RA) group offers regulatory intelligence, strategies, and insights to help our global business units (BUs) address changing regulatory requirements and new challenges for compliance.

What we do:

Support global operations

Managing a complex crisis like COVID-19 requires a strategic and nimble response to challenging and ever-evolving circumstances. The Charles River RA team collaborates with authorities and BUs to address issues, anticipate change, and prepare for the future so that we can continue to meet our standards for the client experience.

Monitor circumstances that could affect our services

In response to the pandemic, many regulators are releasing Emergency Use Authorizations (EUAs) and expedited regulatory pathways for devices, diagnostic testing, and therapeutic providers. Some authorities are reclassifying products to streamline market entry and avoid shortages. The Charles River RA group closely follows and shares these changes with our BUs for optimal handling of ongoing and future programs.

Acquire and apply knowledge

While COVID-19 remains an active pandemic, regulatory agencies around the world are adapting guidelines. There is a degree of alignment among the guidance documents, but we must consider nuances independently. The Charles River RA group educates our BUs on COVID-related regulatory changes so they can maintain compliance while minimizing risks to study integrity.

Offer mitigation planning and help prepare for future business growth

Sharing their Health Authority experience and insights, the Charles River RA group offers timely intelligence, recommendations, and technical support that allows BUs to effectively mitigate the impact of COVID-19 and pave the way for new opportunities.

Examples of Work

Monitoring the global regulatory climate means little without decisive action in response to change. As the COVID-19 crisis continues to influence our industries, the RA group has served its stakeholders in several notable ways.

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Expertise in Action

Since authorities announced the postponement of on-site inspections in mid-March, the Charles River RA group has paid careful attention to news regarding this striking change, with plans to communicate timelines for each agency's return to on-site inspections as they are announced.

RA has updated executive and BU leaders with weekly COVID-19 positive test reports. It is important to note that the Centers for Disease Control (CDC) does not require laboratories to report test results directly to the CDC.

RA has informed global stakeholders of all actions taken by regulatory authorities, i.e., guidance documents and resources for industry regarding COVID-19, and shared information on potential treatments and vaccines.

Regulatory authority highlights:

- The US Food and Drug Administration (FDA) has released, to date, [51 guidance documents](#) related to the COVID-19 response. In addition, they've published [a comprehensive resource page](#) with COVID-19 news, information on personal protective equipment (PPE), virtual town hall meetings, frequently asked questions, and Emergency Use Authorizations.
- The Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK has released, and continues to update, [a guidance document](#) for industry, healthcare professionals, and patients covering the COVID-19 pandemic; the MHRA [resource page](#) contains information on testing, safe working conditions, financial support, and other health and well-being information.
- The Health Products Regulatory Authority (HPRA) of Ireland's [resource page](#) covers medicines, medical devices, and clinical trials and investigations, with respective updates concerning COVID-19.

- The European Medicines Agency (EMA) maintains a [resource page](#) of updates, guidance for industry, information on potential treatments and vaccines, and public health advice. The agency has also created [a COVID-19 EMA Pandemic Task Force \(COVID-ETF\)](#) with the aim of helping EU Member States and the European Commission take quick and coordinated regulatory action on the development, authorization, and safety monitoring of treatments and vaccines intended for the treatment and prevention of COVID-19.

FDA Emergency Use Authorizations

[FDA Emergency Use Authorizations \(EUAs\)](#) are expedited authorizations of medical products and treatments to address public health emergencies such as COVID-19. The Charles River RA group communicates news regarding these important developments to executive and BU leadership weekly, with a primary focus on EUAs granted for COVID-19 diagnostic tests.

During the pandemic, the FDA has worked with more than 400 test developers who have already submitted or said they will be submitting EUA requests to the FDA for tests that detect the virus or antibodies to the virus. To date, the FDA has authorized over 100 tests under EUAs.

Conclusion

The Charles River Laboratories Regulatory Affairs team is committed to sharing timely regulatory subject matter expertise with internal and external stakeholders to help them comply with complex and shifting regulatory guidelines as influenced by pandemic. Keeping our finger on the pulse of breaking regulatory news, we can assess, digest, and share intelligence that is useful, relevant and actionable for our clients and business leaders.

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