Developing Medical Products for Public Health Emergencies

 The 2019 novel coronavirus (coined COVID-19 by the World Health Organization) is the latest in a series of public health emergencies in recent years to challenge product developers in the life sciences community. With every challenge comes an opportunity, in this case to leverage product development plans and technologies to be first-to-market with products useful in remediating some aspect of COVID-19 and its spread. Earlier this year, the U.S. Food and Drug Administration (FDA) announced its commitment to extend all available resources to help expedite the development and availability of medical countermeasures (MCMs) to prevent, treat, or diagnose COVID-19 and, in fact, issued the first emergency use authorization (EUA) shortly thereafter. For life sciences companies exploring potential opportunities to leverage their programs to help treat, detect, or address some aspect of COVID-19, a number of regulatory mechanisms may be available to facilitate and advance product development plans.

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