

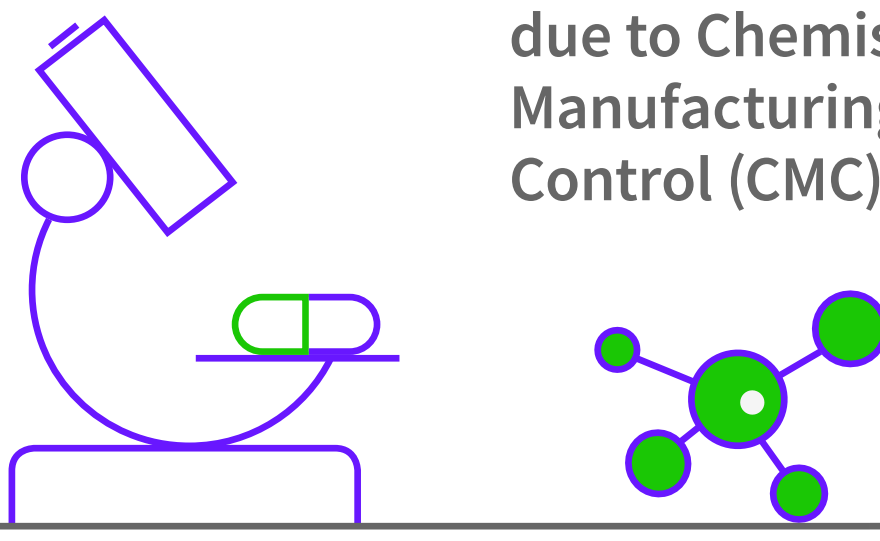
Developing a drug is difficult. Going to market shouldn't be.



50% of first new drug applications filed between 2000 and 2012 were rejected³



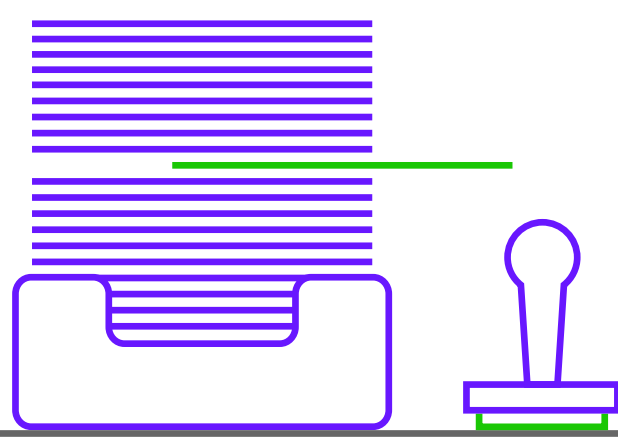
11.3% of which were due to Chemistry, Manufacturing and Control (CMC) issues³



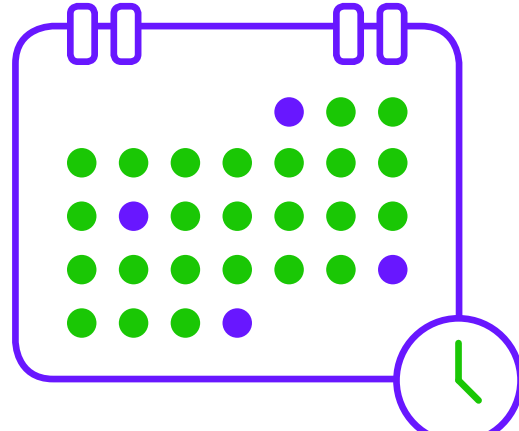
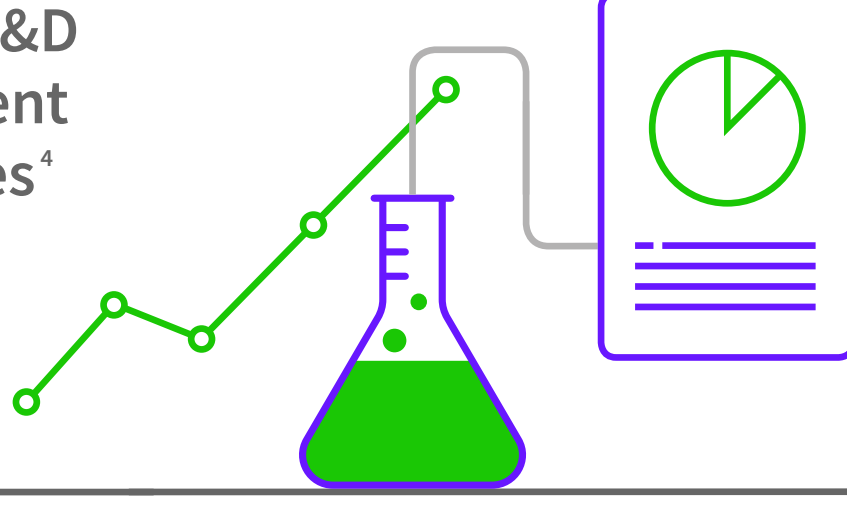
18.3% of resubmitted applications were delayed again due to CMC issues³



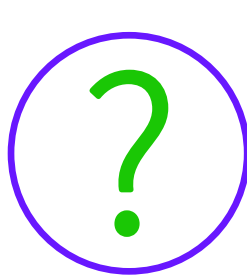
5% of all drugs are never approved due to unmet CMC requirements³



14.8% of total R&D expenditure spent on CMC activities⁴



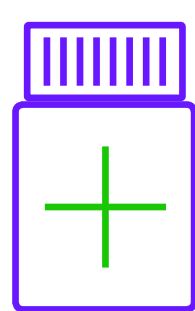
12-18 months to complete CMC activities⁵



Why are there so many delayed timelines and additional costs due to CMC activities?

A lack of reliable, comprehensive and up-to-date information

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¹ http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf

² <https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291>

³ <https://jamanetwork.com/journals/jama/fullarticle/1817795>

⁴ 2018 CMR Factbook from Clarivate Analytics: Drawn from the 2018 R&D Investment Metrics Programme

⁵ <http://www.impactpharma.com/blog/planning-your-nda-or-bla-submission-its-more-than-a-gantt-chart/>

*planned at final content build by 2020