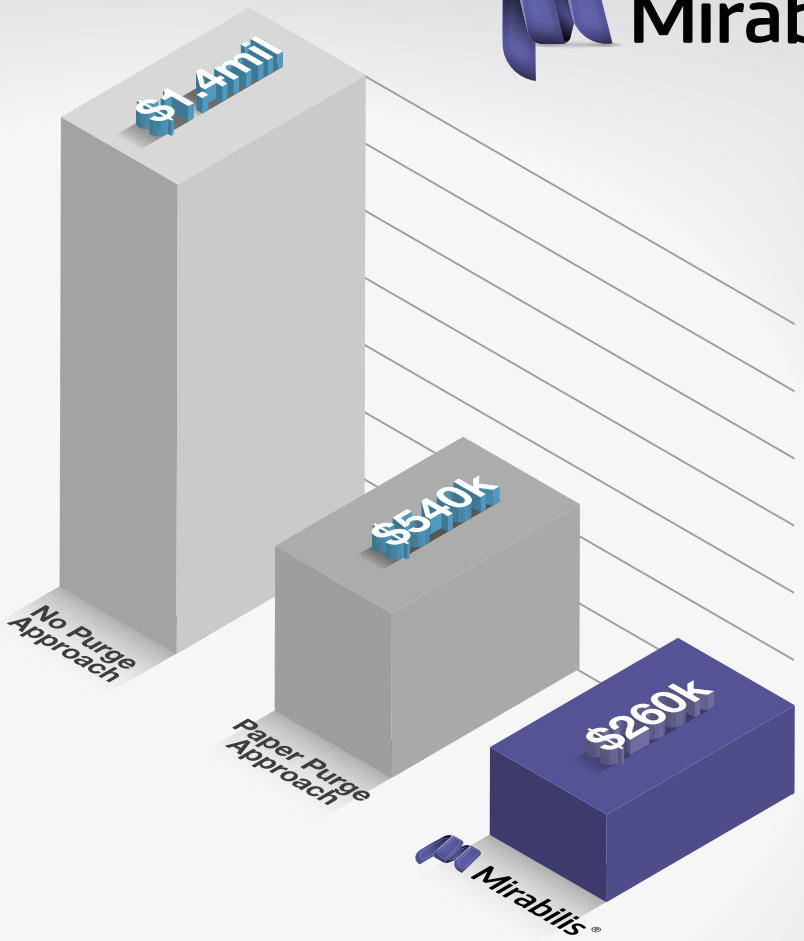
Control your PMI's* using Mirabilis and save an estimated $1.1 million annually

**** Potentially Mutagenic Impurities***

Lhasa has recently worked with a member using Mirabilis to calculate this cost estimate.

We have considered; a medium sized pharmaceutical company, the OPRD paper (linked below) which estimates the number of impurities introduced within a synthetic route, the Lhasa member's analytical workflow for testing for impurities and also the resulting time required for each analytical approach. This time estimate has allowed us to generate an expected cost for development.

Right is an overview of our findings (total spend per year, USD)



The difference in cost shown in the chart, relates to the different control options available to pharmaceutical companies, in line with the ICH M7 guideline, the corresponding required analytical testing and additional studies required for each approach.

By using control option 4 (the paper-based purge calculation approach, detailed in the Teasdale, 2013 publication) with Mirabilis, as opposed to control option 1, a mid-sized pharmaceutical company could save an estimated $1.1 million each year.

There is also a large cost saving generated through using the paper-based approach alone, however not as significant as when this approach is used within Mirabilis.

References

OPRD Paper: Elder, D.P., Teasdale, A., 2015. Is Avoidance of Genotoxic Intermediates/Impurities Tenable for Complex, Multistep Syntheses? Org. Process Res. Dev. 19, 1437–1446.

The ICH M7 guideline: http://www.ich.org/products/guidelines/multidisciplinary/article/multidisciplinary-guidelines.html

Teasdale *et al.* (2013) 'Risk Assessment of Genotoxic Impurities in New Chemical Entities: Strategies to Demonstrate Control', Organic Process Research & Development, vol. 17, pp 221-230. http://dx.doi.org/10.1021/op300268u

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Find out more about what Lhasa's software can do for you!

Find out more about Mirabilis **here**

Request a Mirabilis demonstration **here**