

Asset utilization and cost of non-conformance in API manufacturing

Are hidden analytical costs and process inefficiencies impacting your API production?

Analytical waiting times between process steps and the true cost of non-conforming batches are financial factors most site leaders recognize, yet few measure comprehensively. This assessment helps identify which of these opportunities may have the greatest impact on your operation.

Checklist	Yes	No
Between synthesis steps, do you have real-time measurement capabilities that allow the process to advance once conversion targets are achieved (i.e., you do not need to wait for laboratory results)?	☐	☐
Do you know how many hours per batch cycle are spent waiting for intermediate analytical results, excluding reaction time itself?	☐	☐
In multi-step processes, do you know how many intermediate analytical checks require laboratory testing before synthesis can continue?	☐	☐
Have you ever lost a batch due to a deviation that was not detected in time, such as incomplete conversion, crystallization deviations, impurity excursions, or residual solvent issues?	☐	☐
When a batch fails a specification, do your cost calculations include not only material losses but also rework, investigations, delivery delays, and internal resource utilization?	☐	☐
Are your synthesis vessels fully utilized (no loss of valuable production capacity while waiting for analytical results from the laboratory)?	☐	☐
If analytical waiting times were cut in half, do you know how much additional annual production capacity that could create?	☐	☐
Is the cost of non-conforming API batches formally tracked within your organization (and not handled on a case-by-case basis without annual consolidation)?	☐	☐
Have you compared the cost of your current analytical approach, including sampling, laboratory work, and operator time, with the value of the risks it is intended to mitigate?	☐	☐
If a feasibility study using your own process samples demonstrated reduced analytical waiting times, would you evaluate the potential return on investment?	☐	☐

How to interpret your score

8–10 Yes answers – You have strong visibility into both cost areas. Let's explore how inline Raman spectroscopy could enhance your existing operation.

5–7 Yes answers – You have some visibility into both cost areas. A 30-minute discussion could help identify the most accessible short-term opportunity.

0–4 Yes answers – These costs are likely underestimated. This is precisely the type of organization where a Raman feasibility assessment can deliver the most value, without requiring confidential production data.

Discuss these opportunities with an Endress+Hauser application engineer.

Contact us today