

# Batch Release Reimagined

## Transforming Review Timelines and Team Collaboration

A pharmaceutical Contract Development and Manufacturing Organisation (CDMO) engaged Urmi Quality Management Consulting to resolve ongoing delays and inefficiencies in their Batch Manufacturing Record (BMR) review and disposition process.



The issues were not only disrupting internal workflows but also impacting customer satisfaction and financial targets.

# case study

### Challenges

- No defined timelines for batch release, resulting in prolonged review and disposition processes
- Unresolved deviations as production teams moved rapidly to new assignments
- Customer dissatisfaction due to delays in product availability
- Inconsistent review practices between teams, leading to repeated reviews and internal tension
- Frequent BMR recording errors undermining trust in data integrity
- Project managers missing key financial milestones due to delayed batch release
- A rushed, reactive approach to batch release, compromising quality and increasing complaints

### Approach

- Reviewed the end-to-end batch manufacturing, review, and release process
- Mapped process timelines and identified delays at each stage
- Led cross-functional brainstorming with QA, QC, and production teams to uncover communication gaps and process inconsistencies
- Highlighted commonly repeated batch errors to inform targeted improvements
- Defined clear, stage-specific review timelines and aligned responsibilities
- Facilitated joint training for production and QA teams to promote shared understanding
- Developed a streamlined procedure with embedded checklists for consistent batch review

## RESULT

A standardised and efficient batch review and release process

Noticeable reduction in BMR errors, boosting reliability and reducing review cycles

Stronger collaboration between QA and production teams, reducing friction and improving morale

Timely achievement of project milestones, supporting business performance



### Conclusion

Through Urmi Quality Management Consulting's focused process review and cross-functional engagement, the CDMO transformed its batch review process from a disjointed, reactive effort into a structured, efficient system.

With clearer expectations, reduced errors, and improved team synergy, the organisation now meets critical release timelines while enhancing both compliance and customer confidence. This success underscores the power of tailored solutions grounded in collaboration and process clarity.