



**Built by Advanced Therapy  
Manufacturers for Advanced  
Therapy Manufacturers**



Pragmatic software solutions for  
Advanced Therapy manufacturers

## The industry



### Scalability

Scalability and ramp-up of your manufacturing are dependent on flexible staffing, operations, and materials availability. How do you plan to use your space most efficiently? How will you get there?



### Operations

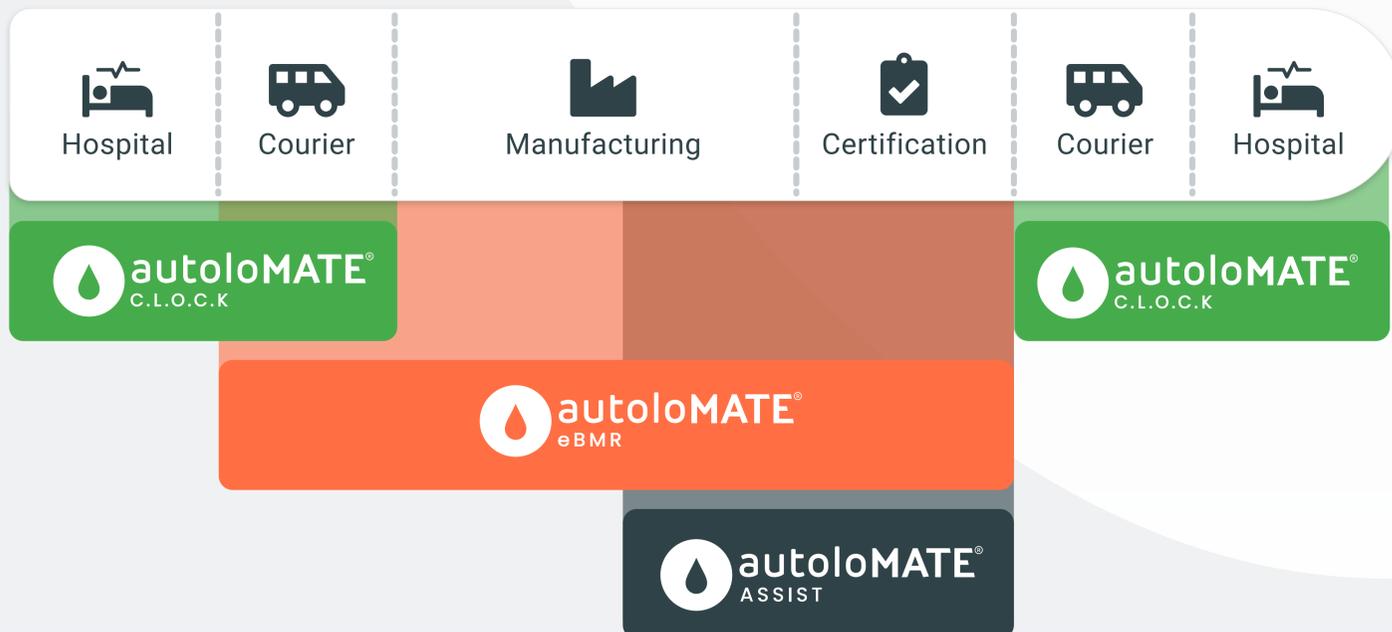
How will you meet the various quality regulatory requirements across multiple jurisdictions while maximizing your workforce? How will you certify batches for international use with the highest levels of compliance across your sites? Can your quality staff flex from product to product or site to site thanks to a fully transparent manufacturing system?



### Insight

A lack of data transparency from early clinical phases to later stages delays regulatory filings. Do various internal and external manufacturing facilities drive product availability in a similar manner or are there inherent differences? How do you show comparability across the product life-cycle?

## Autonomous end to end service offerings



### Flexibility - out of the box

AutoloMATE eBMR can be configured for all types of advanced therapy workflows, including Autologous or Allogeneic. As the process changes, you have control over adapting your eBMRs.



### Automation - calculations & validations

By automating key parts of manufacturing such as running calculations, transcribing data, AutoloMATE eBMR speeds up processes, eliminates errors & improves inter-department communication.



### Compliance - access control & audit trails

Through extensive logging features and role segregation, all activities can be tracked. Data handled is safe and secure and manufacturers are supported in demonstrating their compliance.



### Data analytics - manufacturing insight

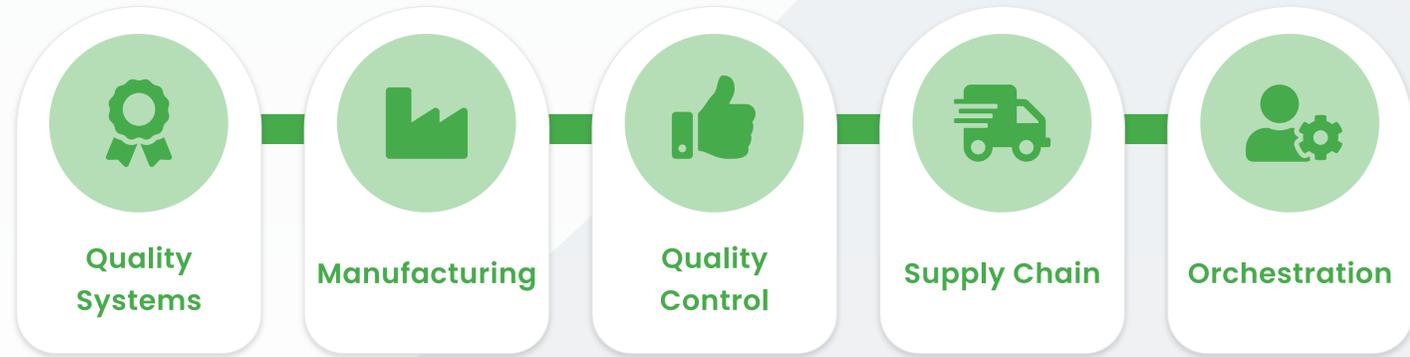
AutoloMATE eBMR streamlines the management of manufacturing data, by integrating siloed information into one digital platform. This allows for learnings to be identified and leveraged to achieve production optimisation and scale-up.



### Deviation management & stakeholder transparency

AutoloMATE eBMR can be set up to raise quality events in your QMS and can enable real-time event notification and resolution across multiple stakeholders: QA, QC, Manufacturing.

## AutoloMATE enables an agnostic digital ecosystem



AutoloMATE® is open and flexible for integrations with industry partners across these product delivery pillars. Numerous integration partners are found in every pillar.



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As an early adopter of the AutoloMATE® platform it has been empowering to work together to deploy our digital strategy. We joined the AutoloMATE® network because of Autolomous' forward thinking product vision and execution experience.

Troels Jordansen,  
CEO of Glycostem



## Security at the core



ISO/IEC 9001:2015 & ISO/IEC 27001:2013 certified  
Cyber Essentials certified



Driven by 'security by design' principles



AutoloMATE® is designed to comply with UK MHRA, EU EMA & US FDA regulation and guidance

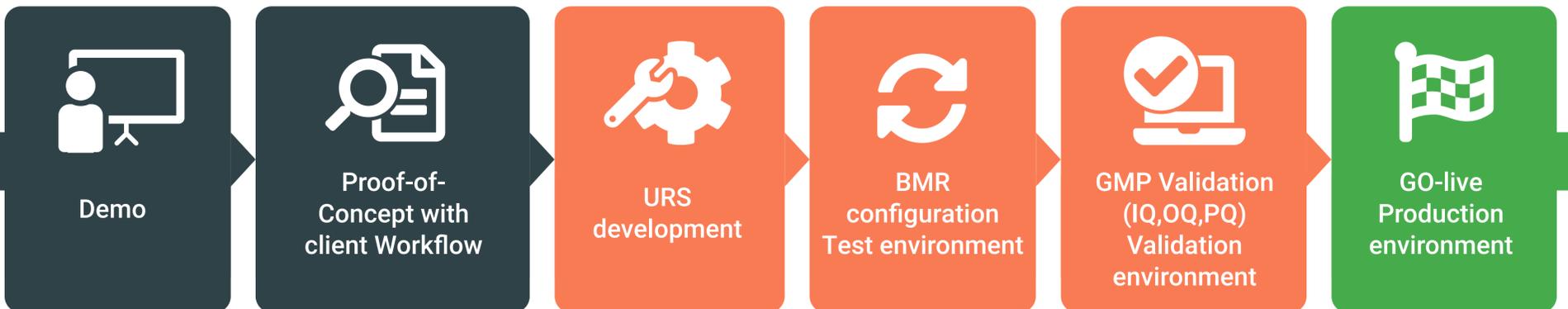


AutoloMATE® has the highest industry security standards: SSO, 2FA, permission segregation and data encryption



Annual penetration testing

## Engagement roadmap



Powered by



## Existing client partners



autolomous

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