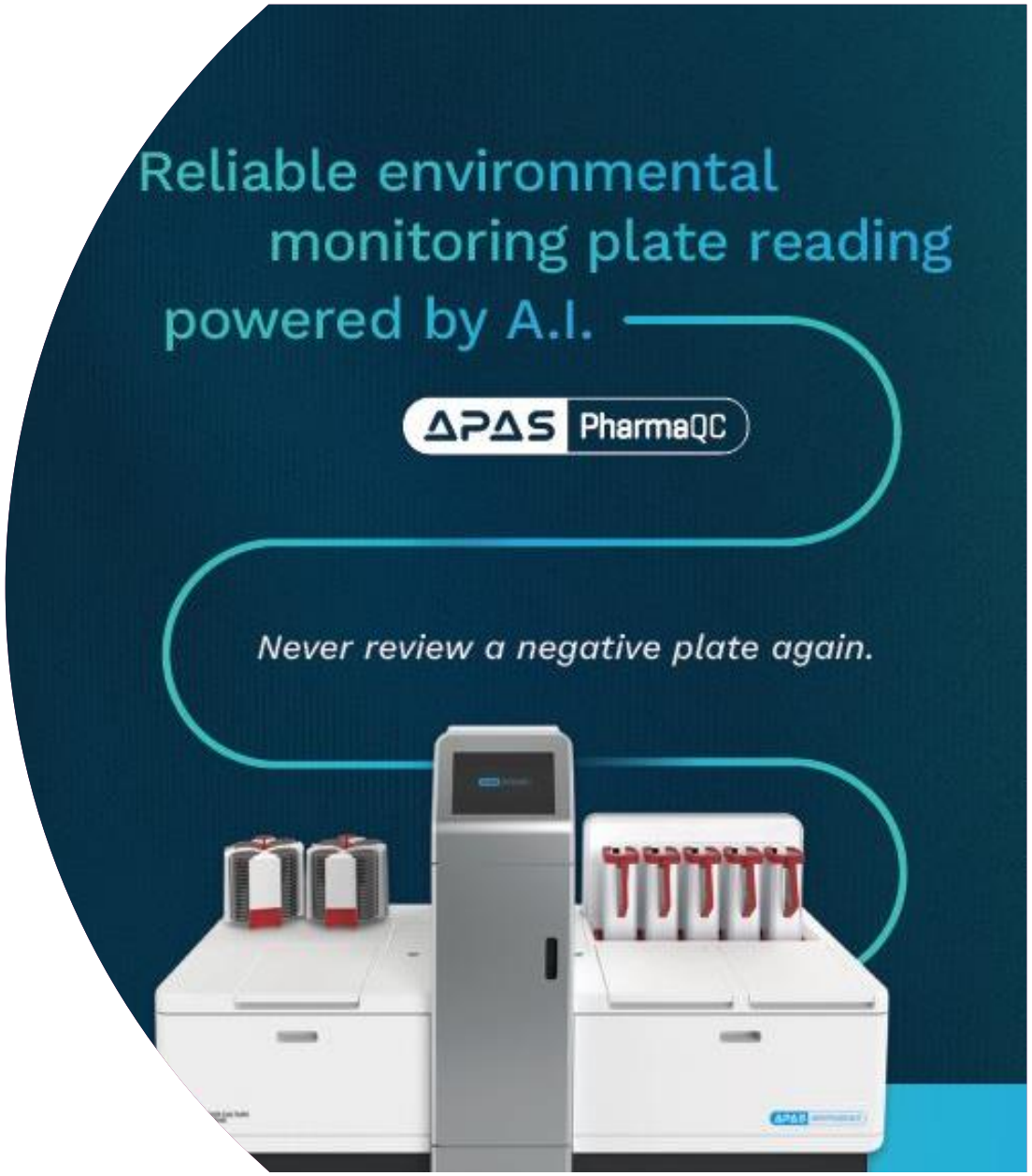
AstraZeneca

GMP–PHARMA CONGRESS

Automated Reading of Agar Plates using AI



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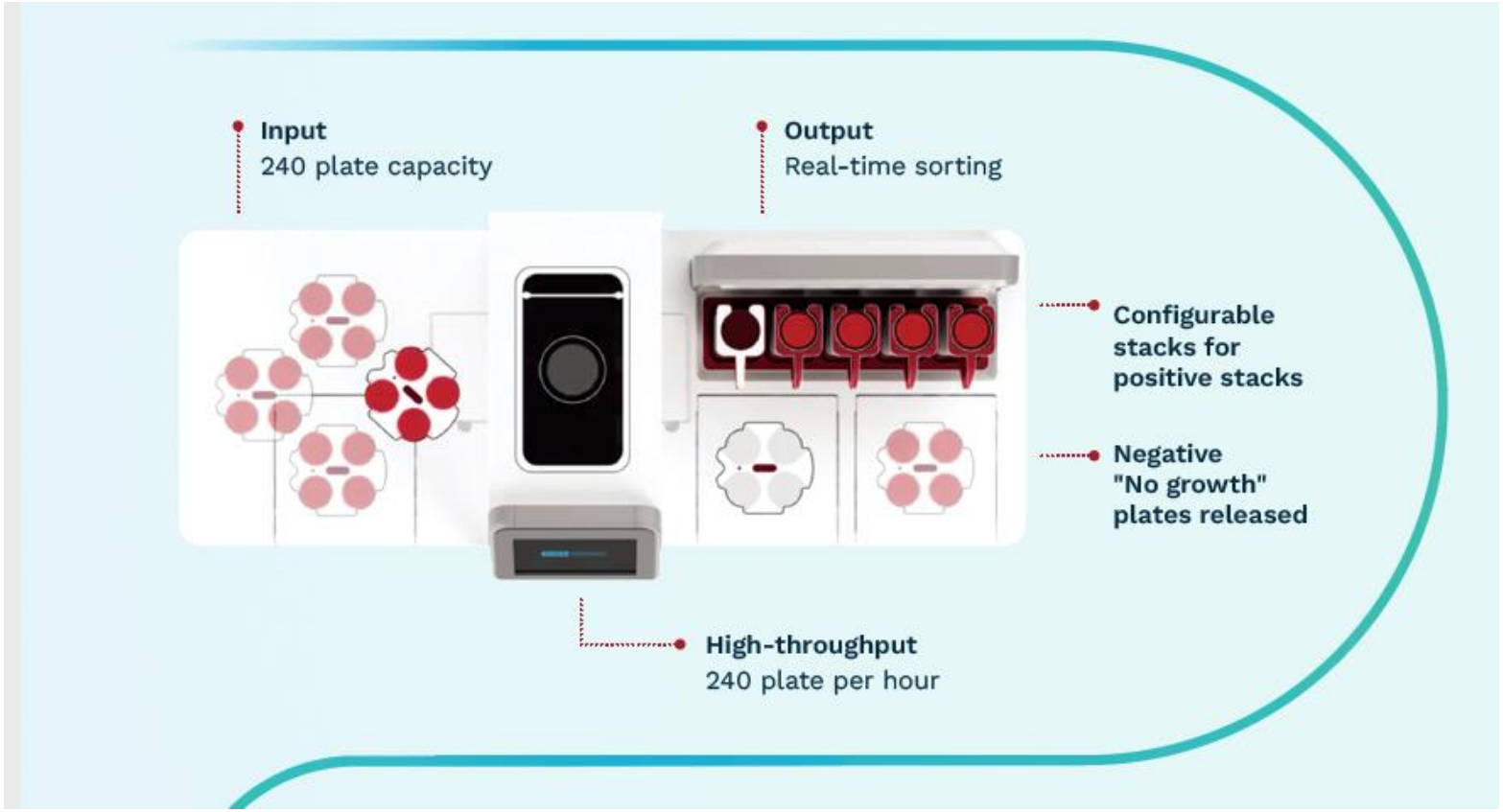
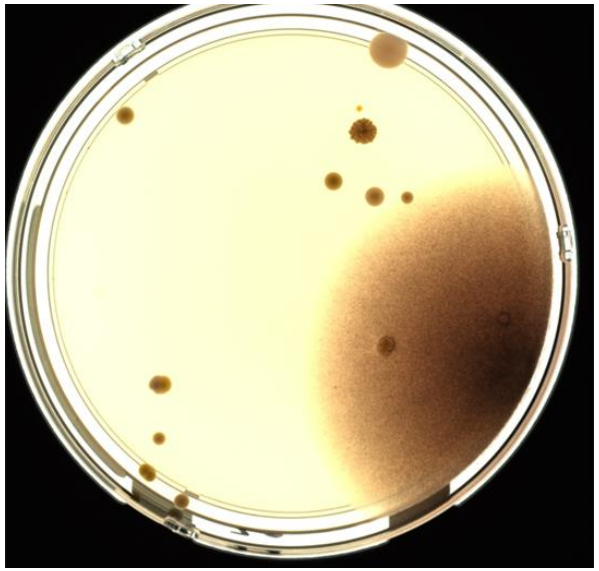
Introducing APAS

APAS (Automated Plate Assessment System) Independence, by Clever Culture Systems (Adelaide, Australia), is an automated plate reader that uses a camera system and AI/ML model to count and sort plates.



Why were AstraZeneca interested?

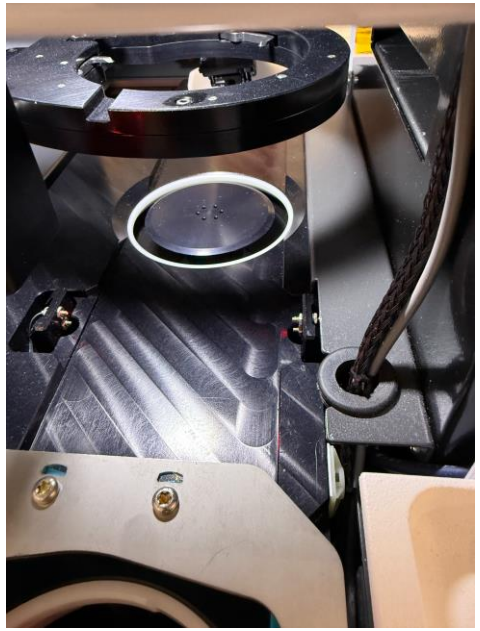


- Up to 30,000 agar plates are manually read and verified at large AZ sites
- Approximately 98% of these are negative (no growth)
- **A task requiring automation**
- Evaluated all available systems. Needed one which wouldn't require huge changes to existing infrastructure/processes:
  - Would work with numerous suppliers' petri dishes
  - Could cope with our numbers (without additional incubators)
  - Gave additional benefits of efficiency and data integrity
  - Could cope with different incubation protocols
  - Could save images/decisions if needed
- The solution was APAS – already approved use of AI/ML for clinical sample analysis.
- **We asked "Could AI/ML also be used to sort and count growth on Environmental Samples?"**

How does APAS Work?

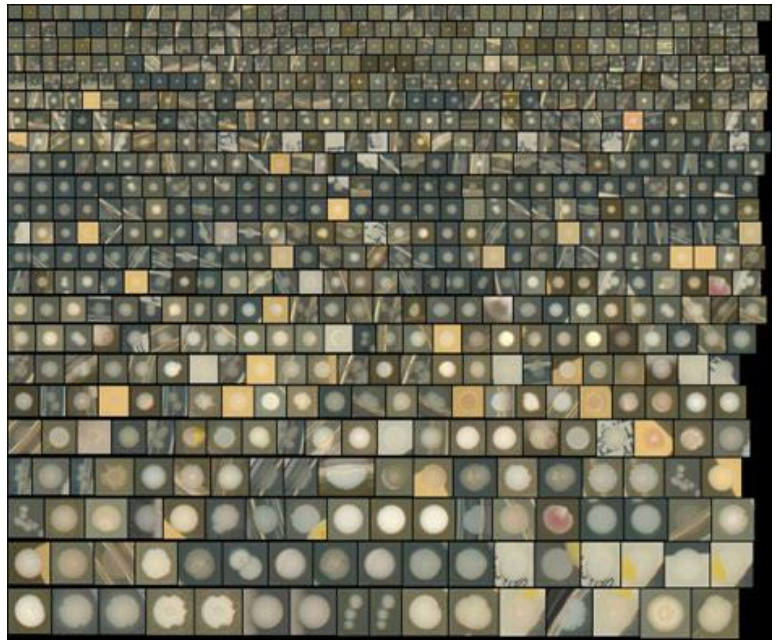
- **What is Artificial Intelligence in this instance?**
  - Basically a mathematical black box.
  - Algorithm developed to make decisions on images of agar plates
  - Based on the images it will decide if an EM agar plate is negative “No growth” or positive “Growth” or “contains artefacts”. Latter two sent for review by microbiologist.
- **But how does it decide?**
  - The black box is ‘trained’ (algorithm developed) to categorise what each pixel in the image is, based on a training set of images.
  - This is a long process of input pixel by pixel by microbiologists, and then testing the response to different ‘test’ plates/images.

How is the algorithm developed?



- The algorithm is ‘trained’ in what the agar background looks like.
  - This is done by showing lots of images of different agar manufacturers agar plates and ‘labelling’ each artifact as background.
  - When APAS then detects these artefacts in real conditions, it will assign these pixels to the ‘Agar Background’ bucket.
  - The algorithm is then developed further by presenting it in training mode with lots of plates/images of different colony types.
  - It is then trained to put these colony types into a different segregation bucket nominally called ‘White colony’, ‘Yellow colony’, ‘Filamentous Fungi’, ‘Transparent Colony’ or ‘Precipitate’
  - AZ shared images of ‘real’ environmental monitoring plates to train the algorithm in additional background and colony data.

Development of the Project and approach to validation and rollout



- Performed a proof of concept on an early prototype AI model
- Partnered with CCS to develop an Analysis Module to meet our automation needs of determining real microbial growth on agar plates and sorting them into separate stacks
- This can potentially save 80-90% of workload and bring other benefits such as:
    - Standardisation across global sites
    - Data integrity and data security
    - Ability to show images of actual plates to regulators
- Started with 90mm plates then repeated the process for 55mm plates once CCS developed the hardware
- CCS performed primary validation to USP<1223>, Ph Eur 5.1.6 and PDA Technical report No.33.
- AZ performed global OQ centrally and then rolled out to AZ sites around the world which then perform localised IQ and small PQ to save effort
- This process has taken 3 years but APAS is now in operation at 5 sites with 3 more at PQ and 2 more at IQ
- APAS is also now in use at other pharmaceutical companies and being evaluated by many more

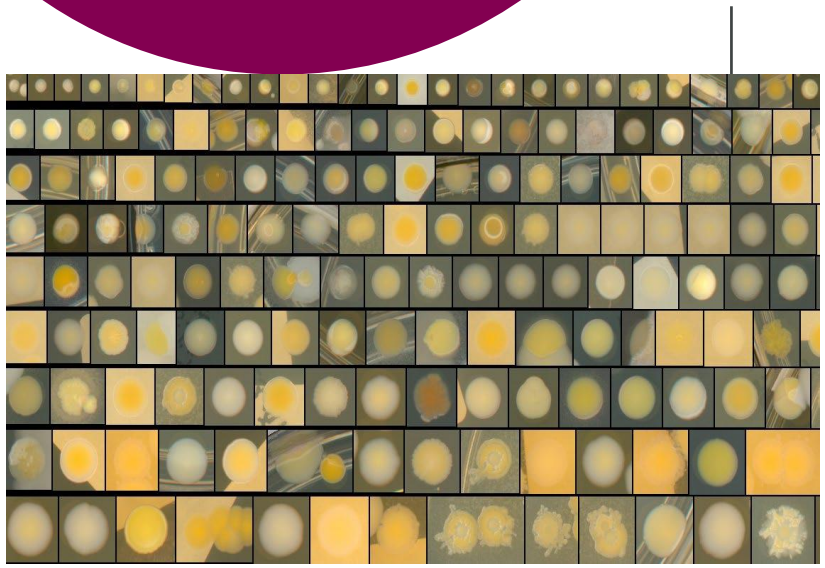
What about compliance?

- Needed to demonstrate that APAS was equivalent to current manual process
- Started conversing with MHRA in early phase of the project via submission to Innovation Centre.
- Presented to QIG (EDQM's Quality Interest Group) at a meeting for companies that were starting to use AI or thinking of using AI.
  - Inspectors from EU, Japan and FDA were in attendance
  - Stated our thoughts on APAS and why we considered that even though it uses AI and ML why we see it the same as any other piece of lab equipment.
  - Stated our thoughts on image retention - 50% agreement across attendees
- Presented to exMHRA consultant and again shared our thoughts
  - He agreed to consult with MHRA colleagues and stated that Innovation Centre had a backlog, so to pursue with MHRA at site audits.
- During routine site audit presented to MHRA inspector
  - Very interested. Listened to our approach, requested slides and said they would discuss with colleagues
- Since Go-Live one site received inspection with focus on use of AI
  - Spent several hours looking at APAS and data.
  - Liked the concept and also the benefits of automation and data integrity

Obstacles

- Started the journey before AI was really known to the man on the street……Would it be accepted?
- What is Raw Data in this case?
- Different views on Image Retention
- Different views on how to validate?
  - Equivalency versus target detection rate
- Lifecycle management
  - Need for periodic revalidation?
  - How to demonstrate no drift – ‘new isolates’
  - How to validate Analysis Module updates
- Have developed a Q and A guidance for common questions asked during interactions and conferences.
- Have Image retention policy.
- Have policy on what is considered raw data with APAS.

What about Data Integrity?



- DI is a key benefit of automation
- Each agar plate has it’s own individual barcode identifier
- Equipment software 21CFR part 11 compliant
- Validated automatic data transfer from APAS to LIMS system – removing error
- Images are retained for 45 days allowing review prior to batch release
- Much improved position compared to manual process which is documented and explained in a risk assessment

Summary

- Long project with many hurdles
- Very worthwhile and more and more benefits and improvements are being seen following implementation
- Don’t be afraid to innovate!

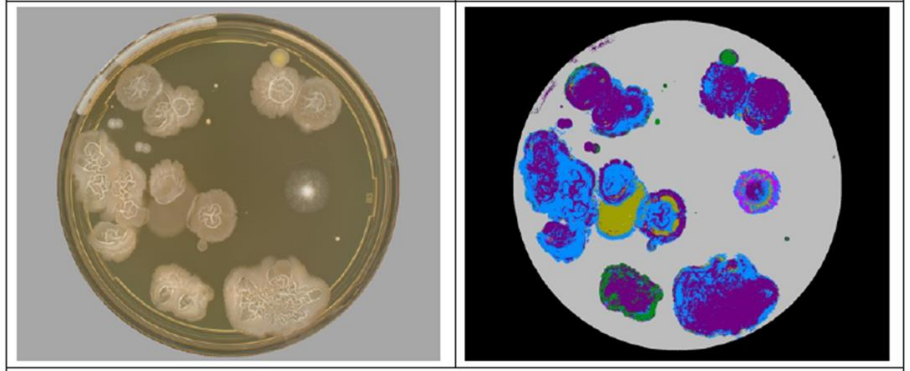
Classifier ‘Buckets’

- White colony
- Filamentous Fungi
- Yellow colony
- Transparent colony
- Precipitate

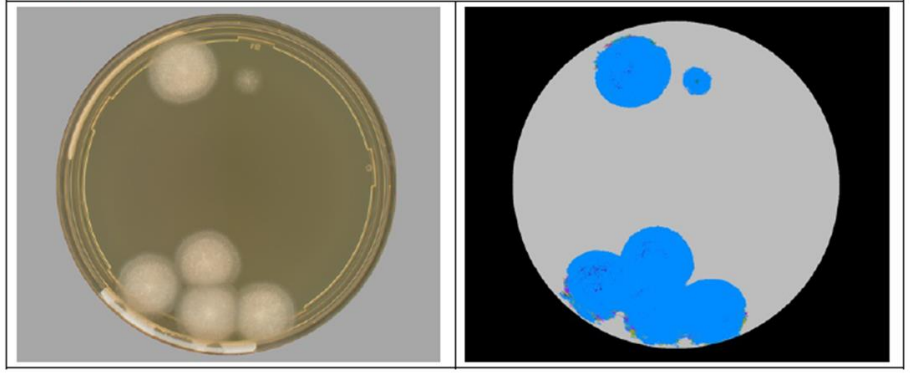
5 CLASSIFIER REVIEW - EXAMPLE IMAGES OF REMAINING ISSUES

The issues around the classifier can mostly be seen in these two examples:

Example 1



Example 2



Individual pixels are not enough to trigger a colony classification. A threshold value must be triggered for a particular ‘bucket’ to satisfy the algorithm that a colony is present.

Thank you for your attention

QUESTIONS ?