

### Regulatory Inspection Readiness

#### The Brief:

Lafferty were engaged by one of our clients to program manage the initial inspection readiness activity associated with a new drug product facility located in Ireland. The program involved the start-up of a newly acquired facility consisting of a single use / ready to use multi-format filling line and associated areas.

The scope of services entailed program management, risk management, and governance of the inspection readiness program in order for the site to achieve a successful outcome from their first (HPRA) inspection milestone. The outcome would be to secure the site's right to operate and first regulatory approval milestone for both commercial and clinical products.

#### The Approach:

Lafferty was engaged by the Site Leader during the start-up phase of the drug product site to oversee and manage the site inspection readiness program.

- Lafferty assumed the role of program manager providing leadership and overall accountability for the inspection readiness program.
- Lafferty reported out twice weekly at Tier 2 level meetings on progress, hot topics/issues, risk and decisions required. The frequency increased to daily within one month of the inspection week.
- Lafferty reported out weekly at SLT governance and bi-weekly above site steering meetings.

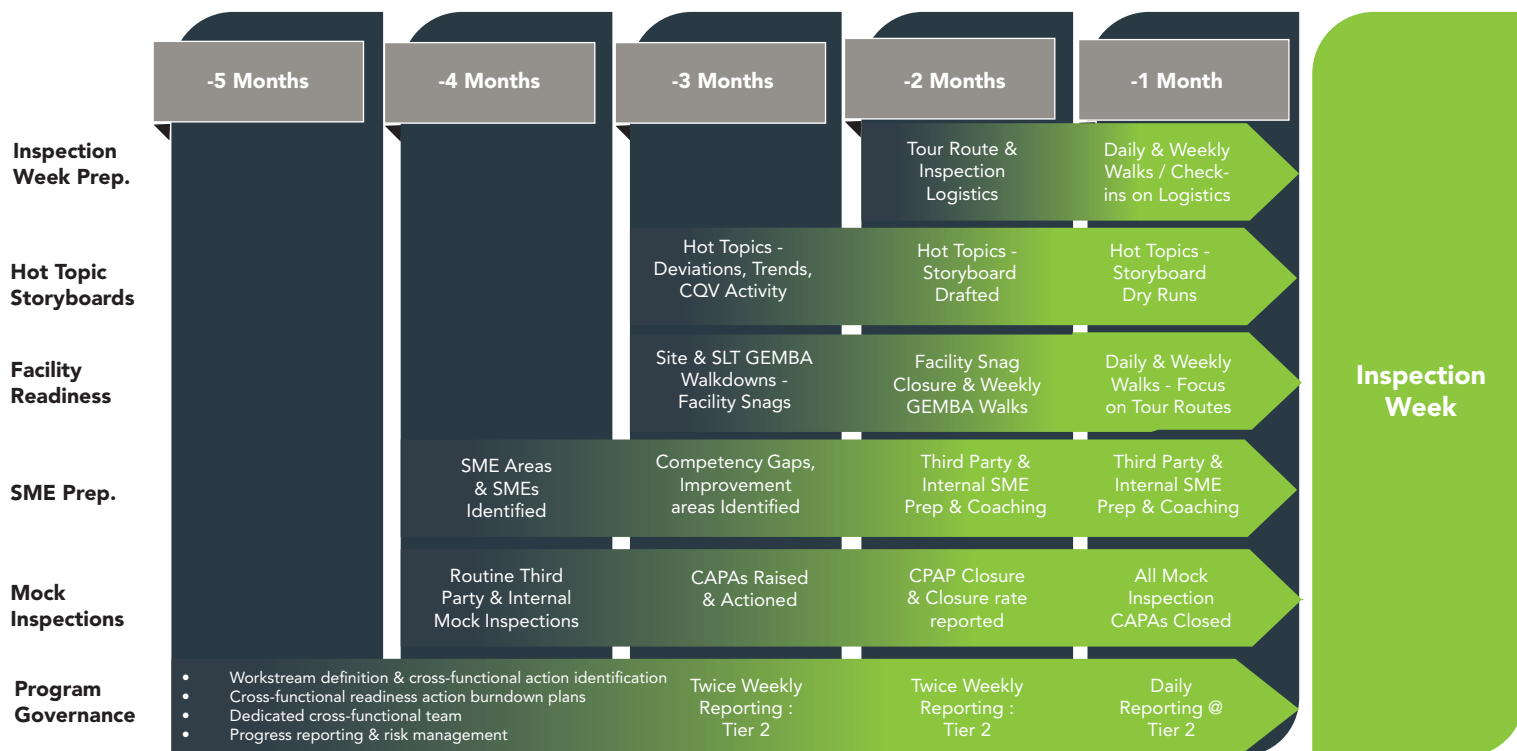
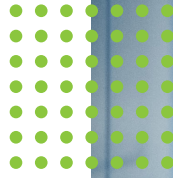


Figure 1: Inspection Readiness Program Approach

### Regulatory Inspection Readiness

- A cross functional inspection readiness team was formed with representatives from quality, operations, engineering, MSAT, and regulatory affairs.
- Six workstreams were identified and scoped out as discreet bodies of work, including: Mock Inspections, SME Preparation, Facility Readiness, Hot Topics/Storyboards, Inspection Logistics, and Data Integrity.
- Mock inspections with ex-inspectors were arranged and facilitated. The findings from mock inspections transferred to CAPAs and tracked to closure, including near misses.
- In-house and third-party SMEs (Quality and ex-Inspectors) were utilised to coach and prepare the site SME's. Both technical and softer inspection behaviour-based training and coaching was delivered.
- GEMBA and SLT site walkdowns were conducted with increasing frequency to snag the facility and building fabric. A facility snag list was maintained and prioritised for closure. Over 400 facility snag items were addressed. Owners and due dates were agreed and assigned to each action.
- A sitewide functional gap assessment and cross walk of procedures and quality systems generated a site inspection readiness action log. A 'burndown' plan was developed to track the action log to closure. Owners and due dates were agreed and assigned to each action. More than 600 action items were closed.
- Hot topics - deviation trends, repeat deviations, CQV issues, technical challenges etc. were identified with story boards developed and reviewed with third party and in-house SMEs.
- A third party specialist was engaged to conduct a data integrity gap assessment across the site which resulted in a remediation plan and associated CAPAs to address gaps identified.
- Inspection logistics and tour routes were identified and prepared in advance of the inspection week. Backroom and IT set-up was tested on dry runs and opening presentation dry runs with SLT.



#### The Outcome:

##### The following outcomes were realised for the client:

- Two inspectors on site for 5 full days conducting a full site GMP inspection for investigational medicinal license and commercial license approval.
- 0 critical findings, 1 major finding, and multiple 'other' minor findings.
- Inspectors complimentary of the team, facility, approach to inspection and overall preparedness.
- Site granted full IMP & MIA HPRA licenses post response to HPRA.
- CAPAs raised and tracked to closure to committed dates including 'near misses' in preparation for FDA Inspection.
- Client has a defined system to manage ongoing and future inspections.
- Client engaged Lafferty on FDA/DAI readiness programme management.



#### Key Statistics:

Location | Ireland

Duration | 6 months

Scope | HPRA/FDA Inspection Readiness

Sector | Biopharma

