

Effective oversight for aseptic preparation Reflections and learning from UHDB

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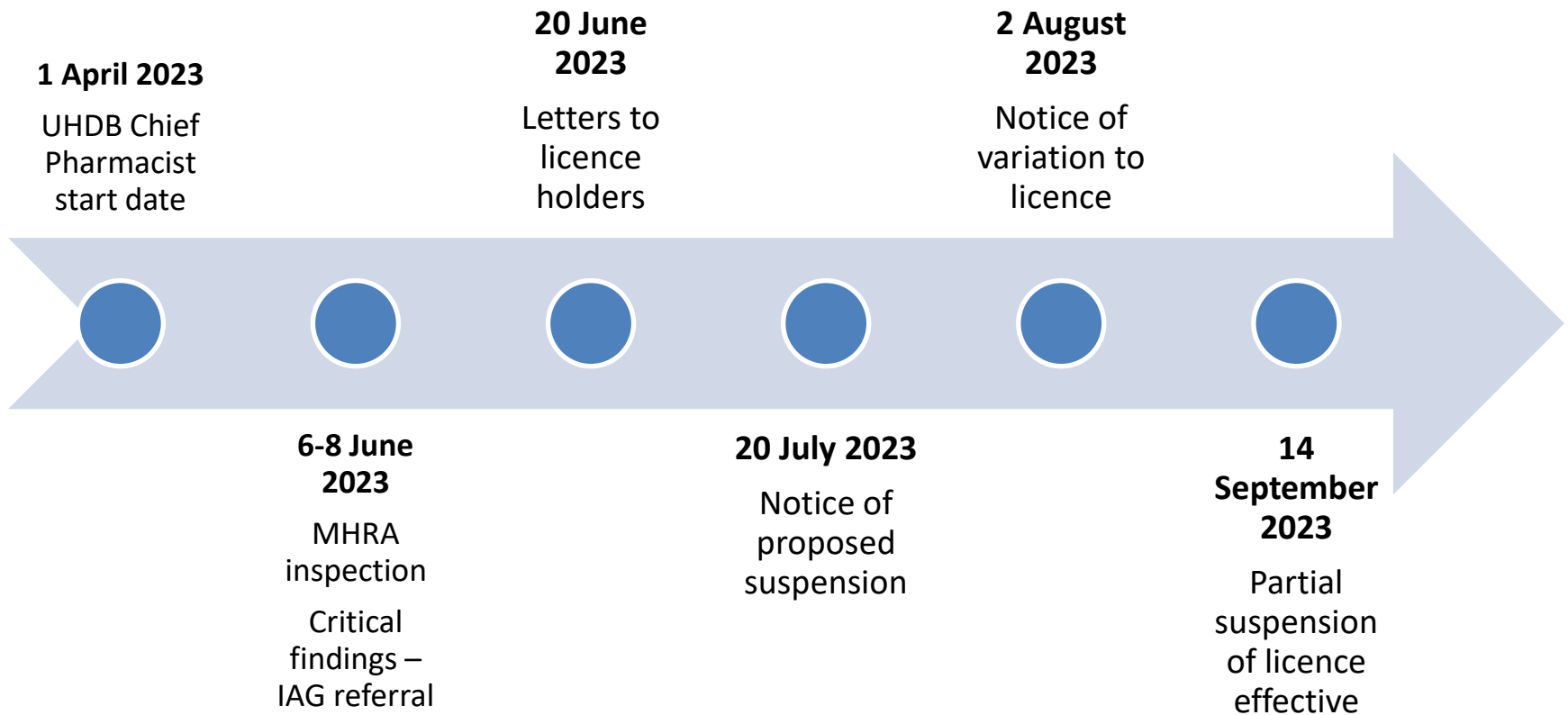
Andrew Reeves, Production Manager

October 2024

UHDB context

- MHRA MS Licence – ready to administer injectables and filled elastomeric devices.
 - For UHDB use and supply to NHS organisations
 - Quality Control (EM) services to UHDB and other NHS organisations
- S10 – 3 aseptic units
 - Chemotherapy at RDH site
 - CIVAS at RDH site (24/7 service)
 - Contingency unit

MHRA Timeline



- Assurance and oversight
 - Last inspection, changing regulatory standards, robust self inspection, external / peer review
 - Reporting, assurance and oversight
 - Escalation routes and reporting within organisation
 - Use of risk register
- Accountable individuals – PM, QC, AP
 - Is licence up to date?
 - Responsibility to support these individuals to deliver their role – training, networking, support, escalation

Chief Pharmacist reflections



Chief Pharmacist reflections

- What is the current understanding of aseptic services within your organisation?
- Does your ICS / ICB understand aseptic preparation and issues / risks?
- How do you balance service delivery and quality? Is your quality capacity adequate?
- Specialist support – Regional QA, SPS, consultancy, other Trusts
- Sharing learning, offering support

Post inspection reflections

Quality Management meetings did not serve the required purpose

- Membership to QMM was not right and did not include the Chief Pharmacist.
- QMM inadequately recorded and no documented process for escalating risks
- Holistic changes required
 - Risk of making changes in isolation limiting impact

‘This is how we have always done it’

Supporting the team

Post audit reflection

- Time to digest the initial inspection, heightened sensitivity or negative reactions
- Acceptance of change, this is paramount to move forward
- Clear action plan, ownership and delegation
- Communicating deficiencies and actions to support staff and wider department

Realistic timeframes and managing expectations

- Timelines need to be achievable
- Expectations of management and support staff will be different
- Prioritising actions
- Positive communication

How do I ensure my Chief Pharmacist is assured?

Quality Management meetings

- KPI dashboard
- Assurance reports

Action plan progress

- Completed actions
- Overdue actions, rational for prioritising specific actions

Escalation and oversight

- Quality Management Meeting escalates through Pharmacy and Divisional Quality and Governance risk groups.
- Oversight of communications with MHRA by Trust governance

Risk register (extreme risk)

- Helpful tool for documenting facility compliance risk
- Supported delivery of Business Case

Support from my Chief Pharmacist

- Clear remit of work
 - Production Manager on MS licence
- Capacity to perform role
- Personal improvement and closing gaps in knowledge
- Business case for facility refurbishment
 - Presenting options and case to trust structure meetings
 - Support external to Pharmacy; finance, project management

To end on a positive.....

- MHRA action plan on track
- AP audits July 2024 – action planning
- Trust support for investment into technical service at UHDB approved July 2024
 - Capital investment for aseptic unit and AHU refurbishment and equipment
 - Staffing resource for service delivery ensuring quality capacity
 - New service model for the future – meeting needs of UHDB patients, high risk medicines