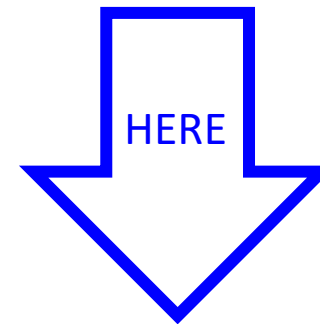


Quality Management Inspectors

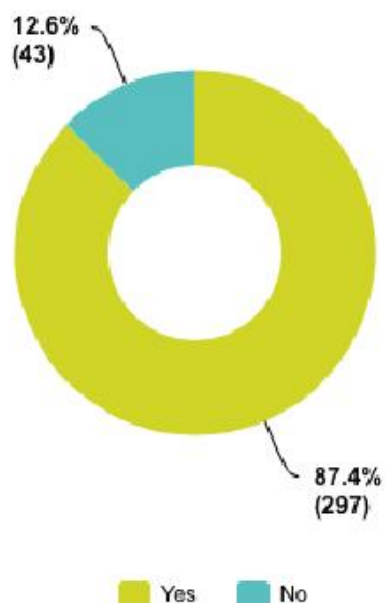


Creating Inspectors Role for Quality Management

Survey Sep-Oct 2014

Should a Quality Manager (QM) be incorporated into the Inspection Team subject to meeting established criteria?

Answered: 340 Skipped: 0



Pilot test

UK
Italy
France

QM Inspector Responsibility

Parts B/CM/C/D 4 QM excluding:

- Outcome analysis
- Tracking & traceability / labeling requirements
- Qualification
- Validation

Parts B/CM/C/D 5 Policies & Procedures

Quality Management Inspectors

CURRENT STATUS

Call for new QM inspectors

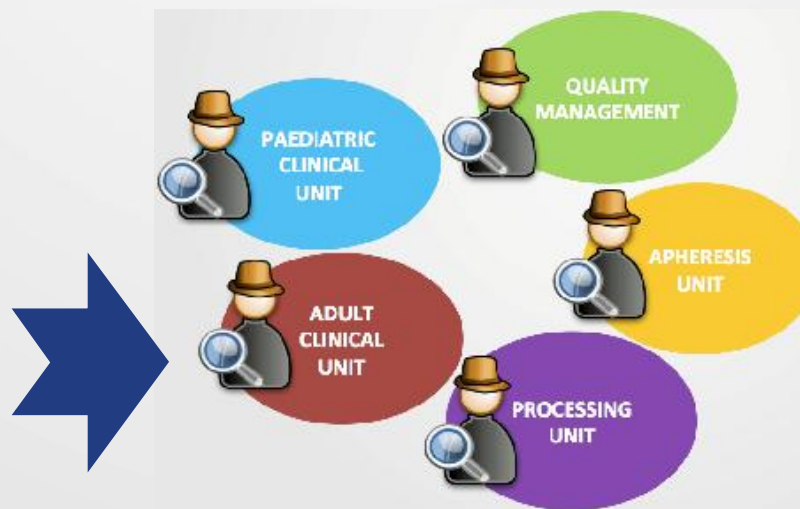
Call to existing JACIE inspectors

- 32 QMI Ready to start inspecting as QMI
- 29 QMI Candidates expected to be QMI by end 2016

- Follow-up required to increase QMI pool
- QMI included, if possible

IMPLEMENTATION JULY 2016 ONWARDS

Clinical Adult & Paed Unit
Bone Marrow Unit
Apheresis Unit
Processing Unit



QMI
Belgium, Czech Republic, Denmark, France, Germany, Greece, Ireland, Italy, Nigeria, Saudi Arabia, Spain, Sweden, Switzerland, Turkey & UK

Quality Management Inspectors



QM INSPECTOR RESPONSIBILITIES

Parts B/CM/C/D 4 QM excluding:

- Outcome analysis
- Tracking & traceability / labeling requirements
- Qualification
- Validation

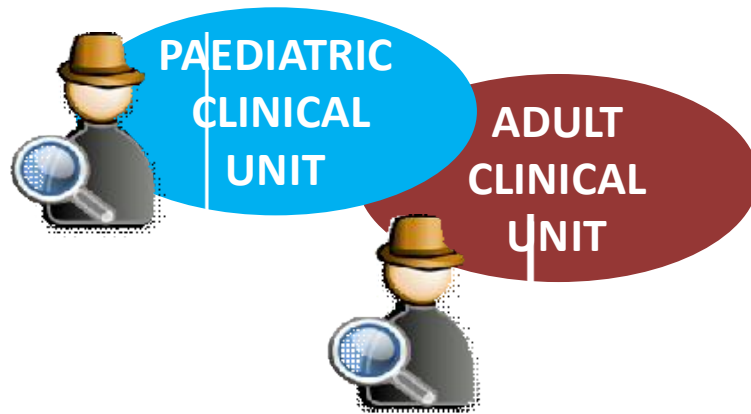
Parts B/CM/C/D 5 Policies & Procedures

Distribution of Standards to be Inspected

Part B/CM/C/D 4 QM excluding:

- Outcome analysis
- Tracking & traceability/labeling requirements
- Qualification
- Validation

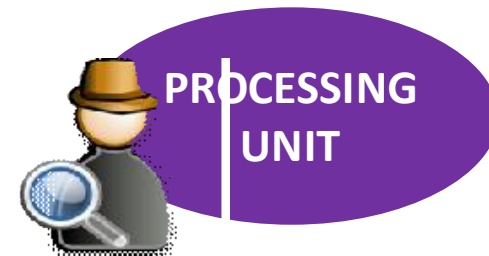
Parts B/CM/C/D 5 Policies & Procedures



Part B + Part CM (- QM)



Part C (- QM)



Part D (- QM)