00. Core Processes

APQC Check	Review	Process Review	Archiate	ORBANK by Jeanne Harmon	ODISEA Archiate	©2018Bizzy by Bizzy, Inc.	Medicines & Healthcare products Regulatory Agency

Core processes

01. Undertake science, research and innovation

- **01.01. Horizon scanning**
  - 01.01.01. Produce horizon scan report
  - 01.01.02. Provide input into Global horizon scanning
  - 01.01.03. Coordinate horizon scan
  - 01.01.04. Produce scientific horizon scan report
  - 01.01.05. Conduct infectious disease surveillance
- **01.02. Biological classicals and control testing research**
  - 01.02.01. Apply for external research funding
  - 01.02.02. Undertake research and development within scientific specialism
- **01.03. Developing biological medicinal products**
  - 01.03.01. Develop standards for Production, Quality and distribution infrastructure
  - 01.03.02. Develop standards for Production, Development and in-licence assessment
  - 01.03.03. Develop standards for Diagnostics
  - 01.03.04. Develop blood safety standards
  - 01.03.05. Develop standards for Pharmacopoeia
  - 01.03.06. Develop a new biological reference standard (Non-Pharmacopoeial Standards)
  - 01.03.07. Obtain ECBS endorsement
  - 01.03.08. Update the NIBSC standards catalogue
  - 01.03.09. Develop Biological IVD
- **01.04. Developing improved biological medicines**
  - 01.04.01. Develop improved biological methods
  - 01.04.02. Develop improved pharmacological methods
  - 01.04.03. Develop improved cell bioage methods
  - 01.04.04. Develop improved molecular biology methods
  - 01.04.05. Develop improved sequencing methods
  - 01.04.06. Develop improved 3Rs methods
  - 01.04.07. Develop improved imaging methods
  - 01.04.08. Develop improved vaccine strain
  - 01.04.09. Conduct structure / function studies
  - 01.04.10. Conduct mechanistic / biological activity studies
- **01.05. Anticipating, preparing for emerging clinical situation**
  - 01.05.01. Assure pandemic preparedness (eg flu)
  - 01.05.02. Support actions for emerging infections / outbreaks
  - 01.05.03. Develop new vaccine for outbreak control
- **01.06. Data characterisation**
  - 01.06.01. Undertake primary care data characterisation
  - 01.06.02. Undertake linked dataset data characterisation
- **01.07. Develop methodologies and tools**
  - 01.07.01. Develop pragmatic trial methodologies
  - 01.07.02. Develop value add tools
  - 01.07.03. Develop primary care data processing methodologies
  - 01.07.04. Develop linked dataset data processing methodologies
  - 01.07.05. Develop new biological test
- **01.08. Conduct commissioned research**
  - 01.08.01. Conduct commissioned observational research
- **01.09. Commission research**
  - 01.09.01. Commission research
  - 01.09.02. Co-ordinate and run collaborative study
- **01.10. Economic assessments**
  - 01.10.01. Develop and publish impact assessment
  - 01.10.02. Produce non-regulatory fees level assessment
  - 01.10.03. Participate in grant award panels
  - 01.10.04. Undertake economic assessments

02. Enable science, research and market innovation

- **02.01. Innovation Office**
  - 02.01.01. Provide advice via innovation office
- **02.02. Obtain and enhance source data**
  - 02.02.01. Add to Electronic Health Record
  - 02.02.02. Recruit data sources
  - 02.02.03. Execute operational data collection from external sources
- **02.03. Provide data services**
  - 02.03.01. Provide observational data services
  - 02.03.02. Perform stage 1A initial assessment
  - 02.03.03. Perform stage 1B detail assessment
  - 02.03.04. Perform stage 2 DSAC
  - 02.03.05. Undertake stage 3 Data linkage
  - 02.03.06. Order CRPD data service
- **02.04. Studies**
  - 02.04.01. Conduct validation studies
  - 02.04.02. Provide interventional data studies

03. Develop a regulatory or scientific framework

- **03.01. Establishment of UK Policy and priorities**
  - 03.01.01. Run UK public consultations
  - 03.01.02. Develop MHRA policy / priorities
  - 03.01.03. Input to OH policy
- **03.02. Evaluate policy effectiveness**
  - 03.02.01. Produce research report with recommendations
  - 03.02.02. Provide scientific support for research report with recommendations
- **03.03. Engage with counterparts on policy development**
  - 03.03.01. Participate in international consultations
  - 03.03.02. Participate in EC working groups
  - 03.03.03. Manage UK component of international group development
  - 03.03.04. Engage with EC and EMA IT systems
  - 03.03.05. Provide briefing to MHRA CEO for HBAC/CABC
  - 03.03.06. Lead / engage in HMA work
  - 03.03.07. Undertake OMCL work
- **03.04. Negotiate EU legislation**
  - 03.04.01. Review and respond to EU draft legislative acts
  - 03.04.02. Manage engagement with European Parliament
  - 03.04.03. Produce notice to EU Groups
- **03.05. Develop legislation for the UK**
  - 03.05.01. Provide policy input to UK legislature
  - 03.05.02. Draft UK legislation
  - 03.05.03. Manage engagement with industry and other actors
  - 03.05.04. Manage development of a refreshed body of regulatory policy
  - 03.05.05. Obtain advice from Government Legal Services
- **03.06. Benchmark and standards**
  - 03.06.01. Develop monographs
  - 03.06.02. Omit monograph
  - 03.06.03. Develop reference standard to support monograph
  - 03.06.04. Contribute to USP Pharmacopeia chapters on biological medicines
  - 03.06.05. Consult on requirements for new or updated standards
- **03.07. Engage in setting other international frameworks**
  - 03.07.01. Contribute to global harmonisation of legislation
  - 03.07.02. Negotiate other international frameworks
  - 03.07.03. Develop and provide UK position
  - 03.07.04. Engage in regulator led activities (ICH, PIC/S, CMRA, MRI)
  - 03.07.05. Engage in global harmonisation of pharmacopoeias
  - 03.07.06. Contribute to WHO guidelines, documents and standards

04. Implement a regulatory or scientific framework into operations

- **04.01. Regulatory assurance**
  - 04.01.01. Develop regulatory policy
  - 04.01.02. Produce guidance on policy analysis
  - 04.01.03. Develop burden reduction initiatives
  - 04.01.04. Calculate equivalent annual net cost to business
- **04.02. Establish and manage organisational capability/ culture**
  - 04.02.01. Undertake internal impact assessment
  - 04.02.02. Develop and agree programme plan of action governance structure
  - 04.02.03. Produce and enforce agreed programme plan of action
  - 04.02.04. Establish organisational unit for BAU
  - 04.02.05. Clarify legislation
  - 04.02.06. Publish best practice guidelines
  - 04.02.07. Develop tools
  - 04.02.08. Produce other documentation/communication materials
  - 04.02.09. Integrate new process into business units
  - 04.02.10. Design new or updated operational processes
  - 04.02.11. Implement new or updated operational processes
  - 04.02.12. Define and design new service
- **04.03. Pre structure and policy**
- **04.04. Develop methods and technologies**
  - 04.04.01. Develop new surveillance methods
  - 04.04.02. Develop new surveillance technologies
  - 04.04.03. Develop new methods for detecting substandard/ counterfeit biologicals

05. Enable compliance with regulations

- **05.01. Determine authorisation**
  - 05.01.01. Register Device(s)/ Product(s)
  - 05.01.02. Action refusal of UKCA Certificates notification
  - 05.01.03. Publish Device Registration Details in FARD
  - 05.01.04. Determine clinical investigation submission
  - 05.01.05. Upload notified body certificates to EUDAMED
  - 05.01.06. Undertake TSE Consultation
  - 05.01.07. Engage and review external assessor
  - 05.01.08. Inspect Devices manufacturer
  - 05.01.09. Designate or redesignate an approved body
  - 05.01.10. Audit a UK Approved Body
  - 05.01.11. Determine Devices Exceptional Use application
  - 05.01.12. Assess paediatric work studies
  - 05.01.13. Assess paediatric investigation plan
  - 05.01.14. Pre-vet advertising material review
  - 05.01.15. Assess complaints - Product information and advertising
  - 05.01.16. Assess import notifications
  - 05.01.17. Self-serve represented manufacturers
  - 05.01.18. Determine process licence submission
  - 05.01.19. Assess and determine variations
  - 05.01.20. Determine medicinal product submissions
  - 05.01.21. Collate and act on metrics
  - 05.01.22. Request Service Derogation
  - 05.01.23. Conduct panel
  - 05.01.24. Register an Organisation
  - 05.01.25. Determine clinical trial submission
  - 05.01.26. Extend Existing Derogation
  - 05.01.27. Determine status and qualification of person accountable
  - 05.01.28. Support expert committees
  - 05.01.29. Service Humanitarian Request
  - 05.01.30. Self-serve submission of Device(s) / Product(s) for registration
  - 05.01.31. Validate represented manufacturer letters
  - 05.01.32. Determine PRM Designation
  - 05.01.33. Set up EAMS PSM
  - 05.01.34. Notify Agency of marketing a tobacco product
  - 05.01.35. Register distance selling logo
  - 05.01.36. Obtain Expert Committee advice
  - 05.01.37. Determine broker licence application
  - 05.01.38. Determine distance selling logo application
  - 05.01.39. Obtain designation for an Innovation Passport
  - 05.01.40. Develop a TOP roadmap for a submission
  - 05.01.41. Execute against TOP roadmap
  - 05.01.42. Withdraw application for marketing authorisation
  - 05.01.43. Implement change of ownership request
- **05.02. Reference data management**
  - 05.02.01. Manage reference / master data
  - 05.02.02. Run dog reference data integrity check and clean
- **05.03. Account management**
  - 05.03.01. Manage customer account
  - 05.03.02. Perform account due diligence
  - 05.03.03. Update existing customer account details
  - 05.03.04. Manage customer account user
  - 05.03.05. Manage customer account service
  - 05.03.06. Perform service due diligence
  - 05.03.07. Perform due diligence on account users
  - 05.03.08. Manage Account Contacts
- **05.04. Benefit-Risk assessment**
  - 05.04.01. Assess risk management plan
  - 05.04.02. Assess risk minimisation measures
  - 05.04.03. Produce or amend formal assessment report
- **05.05. Produce and sell publications**
  - 05.05.01. Publish Good practice guide (Orange, Green, Purple Book)
  - 05.05.02. Order Good Practice Book
  - 05.05.03. Fulfil Good Practice Book order
  - 05.05.04. Create BP and BAN test
  - 05.05.05. Proof Read BP and BAN
  - 05.05.06. Produce and sell publication
  - 05.05.07. Create text for external publication
  - 05.05.08. Proof Read text from external publisher
- **05.06. Produce and sell Reference standards**
  - 05.06.01. Produce Chemical Reference standards
  - 05.06.02. Order reference standard
  - 05.06.03. Order biological reagents
  - 05.06.04. Fulfil order for reference standard
  - 05.06.05. Procure raw materials
  - 05.06.06. Assess lab reports
  - 05.06.07. Monitor metrics
  - 05.06.08. Analyse and report on raw materials
  - 05.06.09. Produce vials for sale
  - 05.06.10. Ship reference standards
  - 05.06.11. Source biological starting material
  - 05.06.12. Produce and pack biological standard
  - 05.06.13. Fulfil order for biological reference standard, biological reagent, IVD or Control Standard
  - 05.06.14. Produce and pack biological IVD
  - 05.06.15. Produce and pack contracted biological standard
- **05.07. Participate in EU regulatory committees**
  - 05.07.02. Present MHRA position
  - 05.07.01. Present MHRA opinion to EU regulatory committee
- **05.08. Testing**
  - 05.08.01. Respond to notification or required analysis
  - 05.08.02. Undertake required biological medicines or substance analysis
  - 05.08.03. Produce test analysis report
  - 05.08.04. Undertake package testing
  - 05.08.05. Undertake counterfeit testing
  - 05.08.06. Undertake CAP testing
  - 05.08.07. Carry out Batch Release Testing
  - 05.08.08. Conduct quality surveillance control survey
  - 05.08.09. Obtain test of non-biological substance
- **05.09. Publish market support information**
  - 05.09.01. Update best practice guides
  - 05.09.02. Update tools
  - 05.09.03. Update training materials
- **05.10. Market authorisation management**
  - 05.10.01. Determine renewal of market authorisation
  - 05.10.02. Assess Labels and Leaflets
  - 05.10.03. Request and analyse sample test results
  - 05.10.04. Assess change to clinical trial
  - 05.10.05. Manage change to device registrations
  - 05.10.06. Collect annual fees
  - 05.10.07. Assess change to clinical investigations
  - 05.10.08. Update CT submission
  - 05.10.09. Track and manage sunset clause
  - 05.10.10. Determine renewal of Medicinal Product Wholesale, distribution, Logo and API
  - 05.10.11. Cancel medicinal product marketing authorisation
- **05.11. Inspection**
  - 05.11.01. Decide on or trigger inspection
  - 05.11.02. Schedule Inspection
  - 05.11.03. Undertake inspection
  - 05.11.04. Support inspections on biomedical or blood products
  - 05.11.05. Conduct Inspection Action Group meeting
- **05.12. Risk assessment**
  - 05.12.01. Post authorisation benefits risk assessment
  - 05.12.02. Conduct post-authorisation device risk assessment
- **05.13. Appeals**
  - 05.13.01. Conduct appeal
  - 05.13.02. Permit or reinstate authorisation, designation or registration
- **05.14. Framework application**
  - 05.14.01. Apply framework for observational research application requests

06. Perform market surveillance and initiate action

- **06.01. Adverse incidents**
  - 06.01.01. Capture and assess adverse incident / Device
  - 06.01.02. Capture and assess ADR / YC / Safety report for medicines
  - 06.01.03. Capture Adverse Incident / YC report for eCigarette
  - 06.01.04. ERMR analysis
  - 06.01.05. Manage signal
  - 06.01.06. Capture and assess Serious Adverse Event Notifications (Blood)
  - 06.01.07. Assess and act on defective medicines report
  - 06.01.08. Investigate incident
  - 06.01.09. Capture, assess and act on GxP report
  - 06.01.10. Capture and assess Serious Adverse Reactions (Blood)
  - 06.01.11. Capture and assess Serious Adverse Event Notifications (Tissues)
  - 06.01.12. Capture and assess PQUR
  - 06.01.13. Manage vigilance activities
- **06.02. Observe market**
  - 06.02.01. Monitor web and advertisements
  - 06.02.02. Monitor UK Approved Bodies
  - 06.02.03. Perform Black Triangle / Intensive monitoring
  - 06.02.04. Assess direct healthcare professional communications
  - 06.02.05. Undertake baselining of another regulatory body
  - 06.02.06. Develop product safety action plan
- **06.03. Monitoring**
  - 06.03.01. Assess impact of communications actions
  - 06.03.02. Assess impact of regulatory actions
  - 06.03.03. Monitor GxP reporting compliance
- **06.04. High profile incident and emergency management**
  - 06.04.01. Respond to high profile incident
  - 06.04.02. Manage actions
  - 06.04.03. Handle contaminated medicines incident
  - 06.04.04. Handle defective medicines incident
  - 06.04.05. Notify relevant stakeholders including other regulators
  - 06.04.06. Conduct scientific investigations into biological public health issues
  - 06.04.07. Work with WHO on Global Health Emergencies
  - 06.04.08. Investigate emergency root cause
- **06.05. Access and analyse observational data**
  - 06.05.01. Obtain and analyse drug exposure data
  - 06.05.02. Conduct post-authorisation safety study
- **06.06. Control adverse clinical outcomes**
  - 06.06.01. Measure and produce immunogenicity
  - 06.06.02. Monitor viral safety
  - 06.06.03. Research and test prions
  - 06.06.04. Monitor vaccine safety

07. Provide information and advice

- **07.01. Provide external advice**
  - 07.01.01. Provide regulatory advice
  - 07.01.02. Provide scientific advice
  - 07.01.03. Provide operational advice
  - 07.01.04. Engage with industry and professionals
  - 07.01.05. Process TREAT OFFICIAL correspondence
  - 07.01.06. Manage enquiry from stakeholder
  - 07.01.07. Provide data consultancy
  - 07.01.08. Provide advice and support for biological standards and control testing
  - 07.01.09. Provide advice to academia
  - 07.01.10. Handle general TPD enquiry
  - 07.01.11. Respond to request for ministerial support
- **07.02. Statutory information**
  - 07.02.01. Develop guidelines
  - 07.02.03. Publish committee publications
  - 07.02.04. Publish guidelines
  - 07.02.05. Produce British Pharmacopoeia
- **07.03. Non-statutory information**
  - 07.03.01. Publish non-statutory information
  - 07.03.02. Prepare information for delivery of medicines and devices
  - 07.03.03. Publish research papers
  - 07.03.04. Publish instructions for use (IFU)
  - 07.03.05. Write scientific papers, articles, chapters in books
  - 07.03.06. Provide non-statutory information
- **07.04. Deliver transparency commitments**
  - 07.04.01. Respond to FOI requests
  - 07.04.02. Monitor agency FOI performance
  - 07.04.03. Manage transparency policy
  - 07.04.04. Respond to media enquiry
- **07.05. Management and reporting**
  - 07.05.01. Compile monthly reporting statistics
  - 07.05.02. Create managers reports
  - 07.05.03. Report monthly management meetings
  - 07.05.04. Report animal work
- **07.06. Respond to legal inquiries**
  - 07.06.01. Produce letter to coroner
  - 07.06.02. Respond to public inquiry, judicial review or legal case
- **07.07. Commitments to Parliament**
  - 07.07.01. Deliver agency products to MPs or Peers
- **07.08. Commitments to ministers and other government departments**
  - 07.08.01. Provide submissions and input to submissions
  - 07.08.02. Coordinate draft correspondence for ministers
  - 07.08.03. QA Wider Agency submissions
  - 07.08.04. Coordinate briefings to ministers and other government departments
  - 07.08.05. Notify devolved administrations to publish BP
- **07.09. Internal correspondence**
  - 07.09.01. Manage response to internal correspondence within timeline
  - 07.09.02. Provide internal regulatory advice
  - 07.09.03. Provide internal scientific advice
- **07.10. Communicate safety information**
  - 07.10.01. Publish Drug Analysis Profile
  - 07.10.02. Produce Drug Safety Update
  - 07.10.03. Provide datasets
  - 07.10.04. Provide CAS Notices
  - 07.10.05. Issue Safety Communications
  - 07.10.06. Publish standards Instructions for Use (IFU)
  - 07.10.07. Issue Product Anonymised Proto (PAPs)
  - 07.10.08. Publish Haemovigilance information
  - 07.10.09. Issue recall of IVD/CF marked devices (intravenous diabetic)
  - 07.11.10. Issue notification of information relating to problems with biological products

08. Encourage compliance with regulations

- **08.01. Research**
  - 08.01.01. Produce behavioural research and recommendations
- **08.02. Inform**
  - 08.02.01. Develop legislation communications
- **08.03. Train**
  - 08.03.01. Develop training materials
  - 08.03.02. Develop training schedule / Calendar
  - 08.03.03. Run training event
  - 08.03.04. Book candidate to training event
  - 08.03.05. Teach / supervise advanced degrees
  - 08.03.06. Order regulator education package
  - 08.03.07. Provide eLearning course
- **08.04. Compliance Promotion**
  - 08.04.02. Develop incentives and nudges
  - 08.04.01. Oversee self regulation of advertising
- **08.05. Compliance Monitoring / Assessments**
  - 08.05.01. Conduct compliance review
  - 08.05.02. Manage compliance case
  - 08.05.03. Notify of intent to suspend / revoke
  - 08.05.04. Disqualify status of GLP Study
  - 08.05.05. Take regulatory action
- **08.06. Monitoring**
  - 08.06.01. Monitor outcomes
  - 08.06.02. Publish paediatric annual reports
  - 08.06.03. Monitor outcomes of enforcement action

09. Enforce regulations

- **09.01. Investigate and assess breaches of regulations / criminal law**
  - 09.01.01. Make determination of an alleged breach
  - 09.01.02. Communicate outcome of prosecution
  - 09.01.03. Assess evidence
  - 09.01.04. Obtain additional evidence
  - 09.01.05. Request support from another Division
  - 09.01.06. Provide support to enforcement activity
  - 09.01.07. Investigate potential criminal activity
  - 09.01.08. Confiscate criminal assets
  - 09.01.09. Review Case - IAG
  - 09.01.10. Support enforcement seizures
  - 09.01.11. Investigate potential regulatory breach
  - 09.01.12. Manage evidence chain
- **09.02. Sanctions**
  - 09.02.01. Require a variation
  - 09.02.02. Determine sanction
  - 09.02.03. Remove product from market (not criminal)
  - 09.02.04. Take action - recall, etc
- **09.03. Criminal prosecutions**
  - 09.03.01. Prepare case for prosecution
  - 09.03.02. Support prosecution
- **09.04. Statutory determinations**
  - 09.04.01. Determine applicable regulatory framework
  - 09.04.02. Conduct review panel hearing
- **09.05. Interruptions and discontinuation**
  - 09.05.01. Provide advice on interruptions to supply and discontinuation
- **09.06. Gather information and turn into actionable intelligence**
  - 09.06.01. Respond to counterfeit medicines report
  - 09.06.02. Assess information relating to alleged breach
  - 09.06.03. Respond to alleged breaches of Devices regulations
  - 09.06.04. Respond to alleged breaches of HMR 2012

10. Support commercial activity of customers

- **10.01. Manufacturer support**
  - 10.01.01. Manage Devices and Products
  - 10.01.02. Offer Certificate of Free Sales
  - 10.01.03. Fulfil CFS Order
  - 10.01.04. Order medicines export certificate
  - 10.01.05. Fulfil order for medicines export certificate
  - 10.01.06. Undertake investigations into biological products production issues
  - 10.01.07. Order Agency supplied tool
- **10.02. Commercial sales and contracting**
  - 10.02.01. Negotiate and agree contract for biological standards fee service
  - 10.02.02. Respond to sales lead and quality