



# **GCC – MARKET RESEARCH**

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# OVERVIEW - GCC

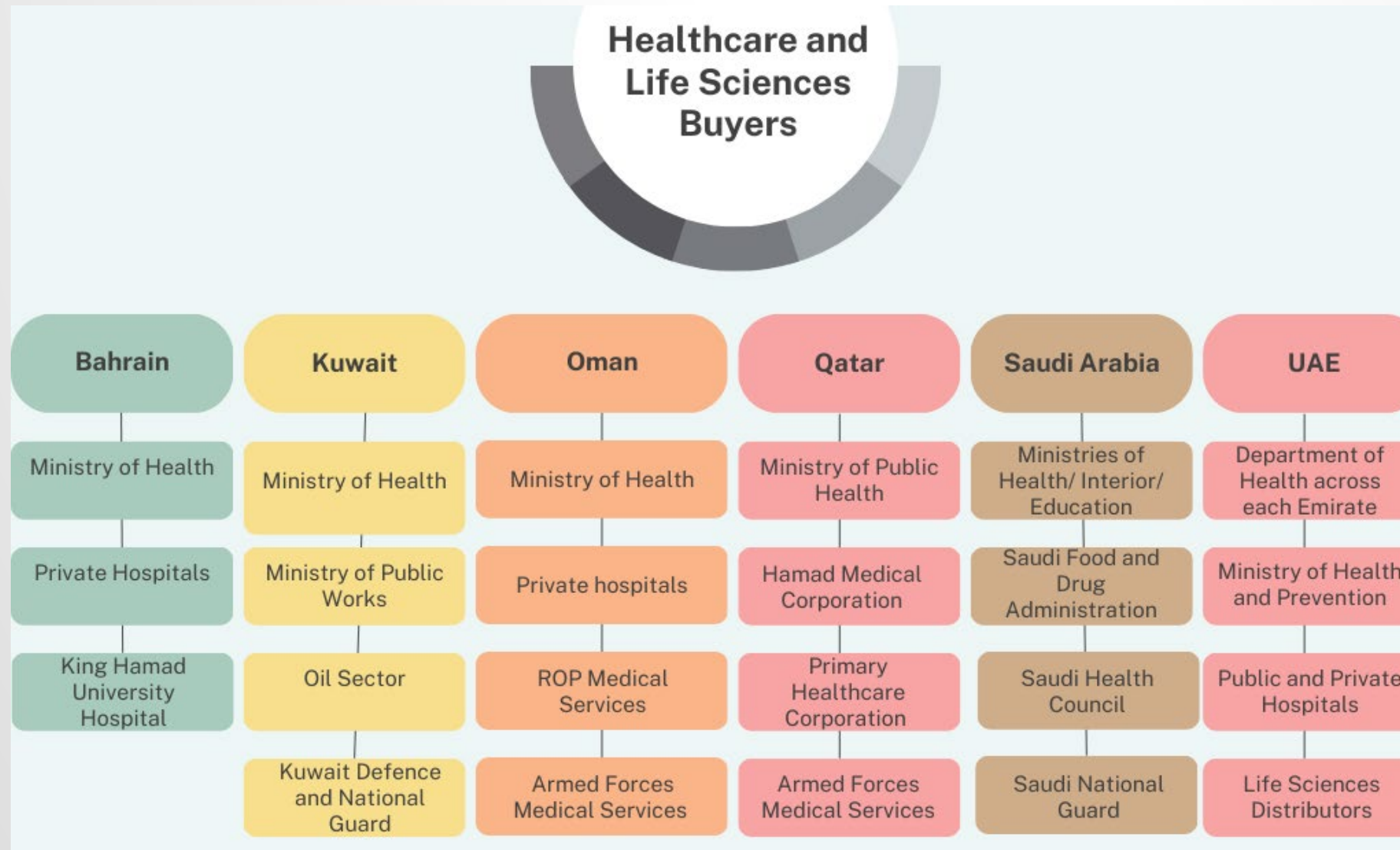
- UK's 4<sup>th</sup> largest export destination outside Europe.
- Six countries in the Gulf Cooperation Council: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates (UAE).
- With an increasing prevalence of lifestyle diseases and ageing population, the HC and LS sector is fast emerging as a priority for countries.
- Second round of UK-GCC FTA negotiations took place between 5 and 9 December 2022.
- UK-GCC bilateral trade in 2020 was worth over £30bn.



# HEALTHCARE AND LIFE SCIENCES - GCC

- Established Healthcare system in the region.
- Medicals Devices – heavily reliant on importation (approx. 75%) predominantly due to lack of domestic manufacturers.
- GCC governments are responsible for setting the policies but also invest significantly in the market, acting as buyers.
- Policymakers drive market priorities with the Vision Strategies and become major private sector clients.
- Where government leads, private corporations will follow.
- UK is very highly regarded in the GCC for the quality of its products and services, but UK firms are considered to be relatively more expensive than other countries.
- Significant demand for UK clinical partners and operators, particularly those with PPP experience.
- Hospitals/doctors based on UK systems or with links to UK hospitals are keen to use UK products and services, but system support is a necessity.

# HEALTHCARE AND LIFE SCIENCES - BUYERS



# CHALLENGES

- Lack of transparency in decision making
- Getting approvals and permissions can take longer and therefore patience is an absolute must.
- Price sensitivity in many areas of healthcare and life sciences
- Understanding local and national laws, customs/ business culture and regulations
- Awareness and understanding about local competition
- Bureaucracy/ Procurement processes
- UAE: fragmented healthcare system with different laws in different emirates
- Negotiations can be lengthy and costly
- Decision-making processes, tendering, contracting and project delivery can be slow often discouraging UK providers—relationship building and consistent long-term engagement is key to securing contracts
- Growing competition from China, India, USA, Germany, Turkey, France

# OPPORTUNITIES

- Increasing interest in **genomics**, which is seen as a key to establishing personalised care and precision medicine while simultaneously addressing need to tackle prevalence of NCDs .
- Increased interest in Robotics, BioTech, Innovative MedTech products, Telehealth and AI.
- Partnering opportunities - Local **vaccine and pharmaceuticals manufacturing ambition** across the region.
- MedTech area growing. MedTech R&D is a focus in Qatar and UAE with startups and live research projects.
- Knowledge transfer is a priority with significant commitments from the region to **invest in the UK's Life Sciences** sector.
- PPP opportunities to increase private sector involvement, by facilitating ownership or management of MoH hospitals.
- Several proposed major private hospitals – looking for international partner (operate hospitals and facilities management)

# DOING BUSINESS IN GCC

- Competition is really high from China and India, making it difficult for companies to enter and operate in the region.
- Proper due diligence and commitment required for long-term success.
- Understand the competitive landscape
- The government has a direct impact on many decision-making processes.
- Business culture is different from EU and US and therefore be prepared to travel regularly (if you don't have a local presence) because they could be called for a face-to-face meeting. Relationship based market
- Be focused, prioritise and be flexible.
- Focus on what is needed in the market and providing solution tailored to the market need.
- Keep yourself up-to-date with local laws and regulations and strategies as things change quickly.
- Social media platforms are used widely throughout the GCC -WhatsApp is a key communication tool, used by everyone.
- Work with your local DIT adviser to understand local culture and opportunities in the region.

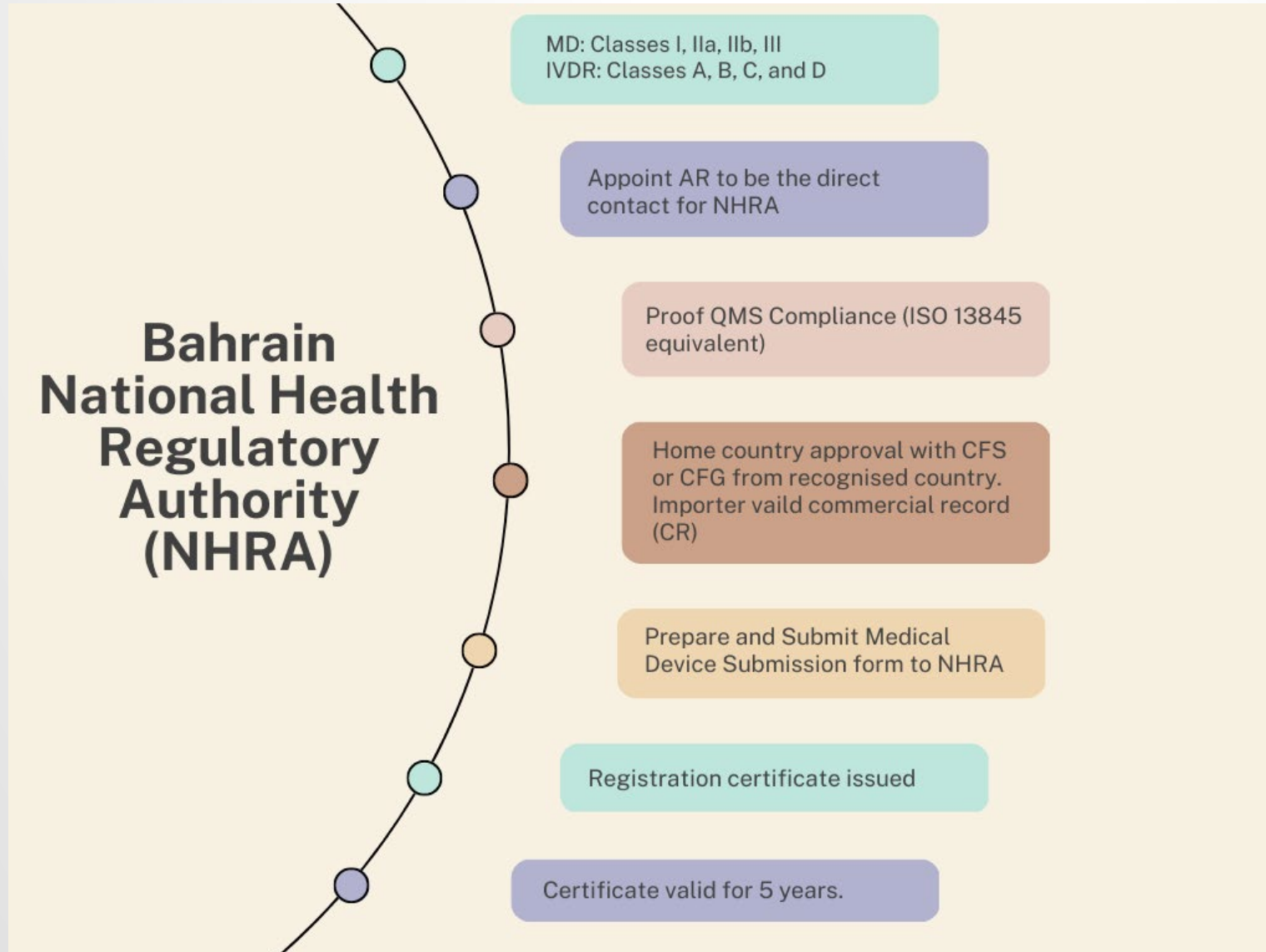


# MEDICAL DEVICE REGULATIONS - GCC

- **Bahrain:** Medical devices are regulated by **National Health Regulatory Authority (NHRA)**. Classification I, IIa, IIb, and III.
- **Kuwait:** Medical devices are regulated by the Drug and Food Control, **Ministry of Health (MoH)**. Classification I, IIa, IIb, and III.
- **Oman:** Medical devices are regulated by Directorate General for Pharmaceutical Affairs and Drug Control, under the **Ministry of Health (MoH)**. Classification I, II, III, and IV.
- **Qatar:** Medical devices are regulated by **Ministry of Public Health (MOPH)**. Currently medical device do not require registration. However, import permit is required. Devices classified according to the EU model: I, IIa, IIb, and III.
- **Saudi Arabia:** Medical devices are regulated by **Saudi Food and Drug Administration (SFDA)**. Classification based on reference country.
- **UAE:** Medical devices are regulated by **Ministry of Health and Prevention (MOHAP)**. Classification I, IIa, IIb, and III.



# DEVICE REGULATIONS - BAHRAIN



# DEVICE REGULATIONS - KUWAIT

## Kuwait: Ministry of Health (MoH)

No risk classification currently in place

Appoint AR to be the direct contact for MoH

Proof QMS Compliance (ISO 13845 equivalent)

Home country approval with CFS or CFG from recognised country. Importer valid commercial record (CR)

Prepare and submit Medical Device Submission form to MoH

Registration certificate issued

Licenses expire with each import

# DEVICE REGULATIONS - OMAN

**Oman: Ministry  
of Health  
(MoH)**

Device classification based on the  
reference county

Appoint AR to be the direct  
contact for MoH

Proof QMS Compliance (ISO 13845  
equivalent)

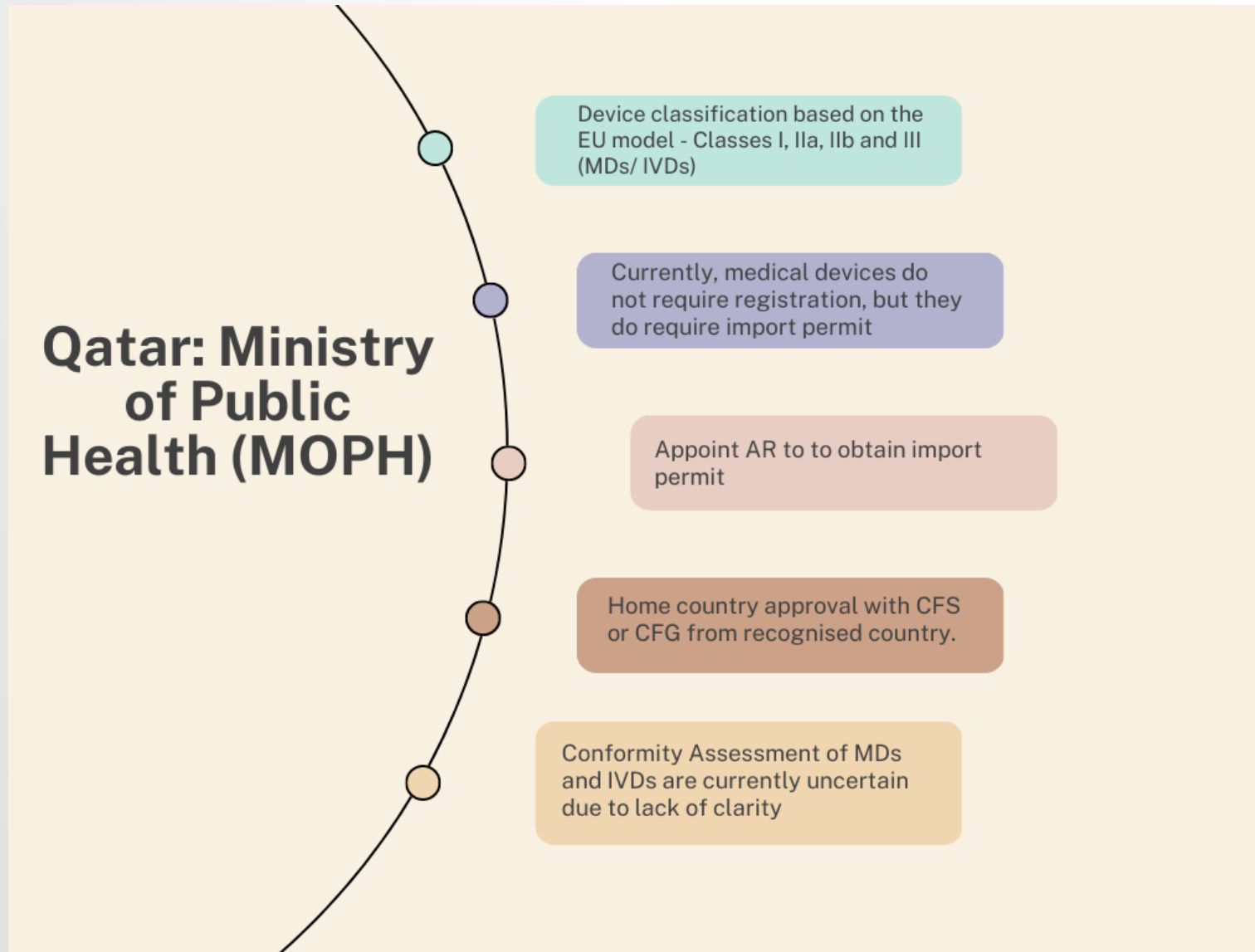
Home country approval with CFS  
or CFG from recognised country.  
Importer valid commercial record  
(CR)

Prepare and submit Medical  
Device Submission form , including  
declaration of Conformity (Doc) to  
MoH

Registration certificate issued

Certificate valid for 5 years

# DEVICE REGULATIONS - QATAR



# DEVICE REGULATIONS – SAUDI ARABIA

## Saudi Arabia: Saudi Food and Drug Administration (SFDA)

Device classification based on the reference country

Appoint AR to be the direct contact for SFDA. AR must be registered with SFDA and have valid license

Proof QMS Compliance (ISO 13845 equivalent)

Home country approval with CFS or CFG from recognised country. Importer valid commercial record (CR)

Prepare and submit Medical Device Marketing Authorisation (MDMA) application, including technical file review

SFDA issues MDMA certificate

Certificate valid for 3 years

# DEVICE REGULATIONS – UAE

**UAE: Ministry  
of Health and  
Prevention  
(MOHAP)**

MD: Classes I, IIa, IIb, III

Appoint AR to be the direct  
contact for MoH

Proof QMS Compliance (ISO 13845  
equivalent)

Home country approval with CFS  
or CFG from recognised country.  
Certificate of Analysis (CoA)

Prepare and submit registration  
dossiers including Declaration of  
Conformity (DoC).

Listing certificate and import  
permit for Class I and Registration  
certificate issued for Class IIa, IIb  
and III

Certificate valid for 5 years

# DIT SUPPORT

## Market Entry Support Services

- In-house assistance by expert advisers
- Market & sector information
- Desk-based market research
- Information on doing business in the MEAP region
- Introductions to partners, agents and distributors
- Introductions to in-market stakeholders
- Information on opportunities and project developments
- Information on tenders and RFPs
- Information on upcoming tradeshow, exhibitions, trade missions and industry events

## Overseas Referral Network

- Company set-up and licensing
- Legal, banking and accountancy services
- Business representation
- Human resources and payroll
- In-depth market research
- Event management
- Public relations and marketing
- Logistics support
- Security services



Thank you.  
Any questions?

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