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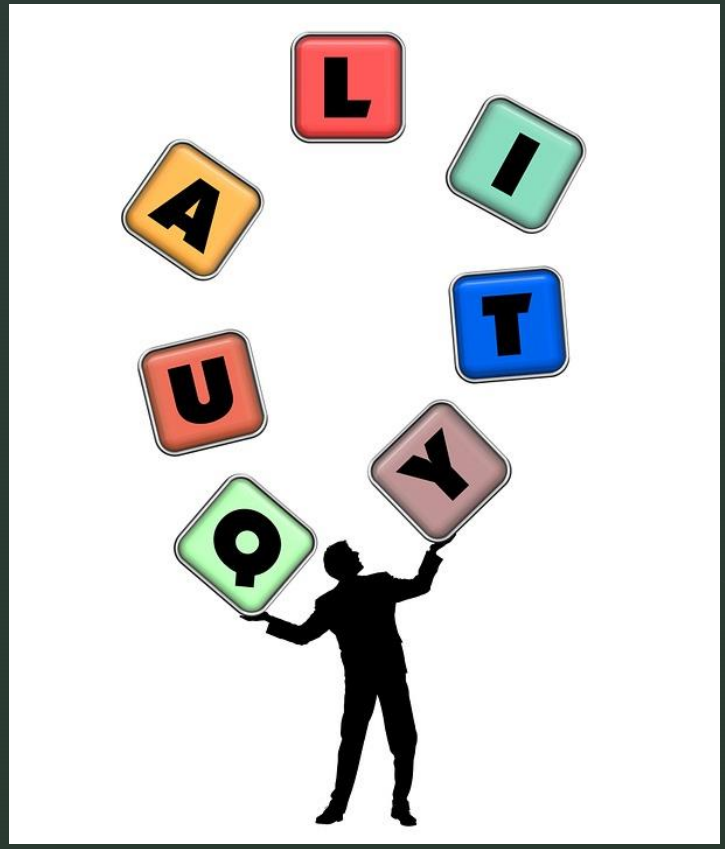
South African Regulatory Requirements

Quick Tips for Local Manufacturers

Bureaucracy



- Each regulator is only concerned with their regulations.
- Respect their sovereignty!
  - No one likes to be considered inferior.
- Ensure that each jurisdiction is probably entrenched within the QMS.

Find common ground

- The majority of requirements are universal, but make sure that you address the differences.
- Careful with the references, terms or ‘language’.
- Find universal standards
  - EN vs ISO vs ANSI vs SANS etc.
- Beware state of the art

Partners

- All CABs or laboratories are not created equal.
- It is not just about price or convenience.
- Accreditations

Tips on choosing a CAB

- Is the CAB willing to be accredited or apply for recognition in South Africa?
- Is the CAB competent with regards to your product?
- Can the CAB help you to gain entry in other markets as well?
  - CE notified body?
  - MDSAP?
  - Third party reviewer?

Prejudice

- Prejudice could go both ways
  - The company is from South Africa and therefore inferior to international companies.
  - The regulator is from South Africa and knows nothing from regulations / medical devices.

Education and respect

- Attitude
  - Knowledgeable but not arrogant
  - Humble but not a push over
  - Pick your battles - don’t nit pick over insignificant issues
  - Treat the auditor or inspector with respect
- Training
  - Know the regulations, standards, processes and product.
    - Proof
  - Webinars – how do your system compare with others?

Embrace

- How does the regulatory requirement (especially if it difficult, resource consuming or arbitrary) add value?
  - If you find the value, you will be more inclined to meet it.
  - It would be easier to get management cooperation.
  - It would justify the resource requirements

Thank you

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