

## Facilitating Smooth and Efficient Medicine Exports - QCS Perspective

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### Agenda

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What is QCS?

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Facilitating Export of Medicines

- Product Quality
- Product Packaging
- Product Labeling
- Product Registration

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QCS Circulars

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Bringing It All Together... and Delivering

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**QCS: Quality Certification Services is a pre-shipment inspection and analysis agency. Currently we serve NAFDAC – Nigeria.**



**Ensuring Product Quality is the primary goal of QCS**

Secondary Goals include ensuring:

- Product Packaging quality
- Product Labeling correctness
- Registration Certificate validity
- Registration Certificate authenticity
- Detection and dissemination of information around illegal activities such as imitations, forgeries, etc.
- Advising Manufacturers / Exporters on Best Practices

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## Product Quality: Product Quality is table stakes, but we still see some common issues...

### Typical Issues

Typical product quality failures occur in:

- Dissolution test
- Assay
- Related Substance test
- Microbial limit test
- Sterility test

### Best Practices

- Comprehensive product development
- Validation of manufacturing process
- Following GMP in totality
- Validation of testing procedure
- Following GLP in totality

Further Reference: QCS Circulars dated 23/1/2003 and 21/4/2008

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## Product Packaging: Its just not attractive clothing; it needs to be a protective armor too...

### Typical Issues

- Leaking bottles
- Bulging cartons
- Liquid suspension bottle with round groove at the bottom
- Cartons without information leaflets

### Best Practices

- Packaging solution should take into account:
  - Nature of product
  - Climatic conditions in exporting country, transit locations and final destination
- Packaging to reduce exposure to counterfeiting
- Tamper evident packaging to reduce risk of contamination / bio-terrorism
- Unique packaging to enable quick recognition for an aging population
- Environment friendly and sustainable packaging solutions

Further Reference: QCS Circulars dated 29/6/2004 and 22/4/2008

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## Product Labeling: Not only an Identiy Card, but also a guide...

### Typical Issues

- Name of drug BP on strip; USP on carton
- Drug registered as USP, labeled as BP
- Batch No. / Expiry Date not legible on blister pack
- Particulars required under drug laws not printed on labels

### Best Practices

- Un-cluttered and easily distinguishable label design to reduce medical errors
- Labels that effectively serve as guides providing essential information to:
  - Patients
  - Pharmacists
  - Doctors
  - Regulatory Agencies

Further Reference: QCS Circulars dated 21/4/2008 and 22/4/2008

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## Product Registration: A Visa without which you cannot enter a country

### Typical Issues

- Manufacture of registered drug at unregistered manufacturing site
- Registration certificate not renewed
- Correct document of registration not available
- Renewal certificate or document not available

### Best Practices

- Renew Product and plant registration before expiration of registration certificate
- Manufacture drugs at registered manufacturing sites only

Further Reference: QCS Circulars dated 7/8/2006, 8/8/2006, 21/8/2009 and 31/8/2009

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## QCS Circulars: He who learns from the mistakes of others is indeed wise....

QCS regularly issues Circulars on commonly encountered issues that delay / result in non-issuance of a Clean Report of Inspection and Analysis. We believe its less expensive to learn from the mistakes of others.

| #  | QCS Circulars   | Dated      |
|----|---|------------|
| 1  | Product Development (Biroxicam Capsule)   | 24/1/2003  |
| 2  | Validation of Manufacturing Process   | 29/1/2003  |
| 3  | Facilitating smooth issuance of Clean Report of Inspection and Analysis (CRIIA) | 1/2/2003   |
| 4  | Product without information leaflets  | 29/1/2004  |
| 5  | Renewal of Registration Certificate   | 8/8/2006   |
| 6  | Manufacture of drug at registered site  | 7/8/2006   |
| 7  | Timely submission of documents  | 26/10/2006 |
| 8  | Replacement samples   | 27/1/2007  |
| 9  | Revision of packing list  | 31/1/2007  |
| 10 | Left over shippers after container stuffing                                     | 20/3/2007  |
| 11 | Treasury receipt for Registration Certification                                 | 5/6/2008   |
| 12 | Faulty formulation  | 21/4/2008  |
| 13 | Printing correct name of drug on all coverings                                  | 21/4/2008  |
| 14 | Clear legible Batch No., Mfg. Date, Exp. Date on strip packs, blister packs,... | 22/4/2008  |
| 15 | Placing blister packs of Batch No. in cartons of another Batch No.              | 22/4/2008  |
| 16 | Leaving from the mistakes of others   | 23/4/2008  |
| 17 | Renewal of Registration Certificate   | 31/8/2009  |
| 18 | Expediting issuance of CRIA   | 31/8/2009  |
| 19 | Copies of all circulars   | 31/8/2009  |
| 20 | Correct documents regarding registration of Product                             | 31/8/2009  |

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**Bringing It All Together... and Delivering: Smooth and efficient Pharma trade is all about focusing on the basics**



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**Thank You**

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