What is QuBAS?

- User-friendly biostatistical software package
- Everything you’d expect...

- Logit
- Probit
- Linear Models
- 4PL Models
- 5PL Models

- Equivalence Tests
- Parallel Line Analysis
- Interpolation Analysis

- Outlier Management
- GMP & 21 CFR Compliant
What is QuBAS?

- User-friendly biostatistical software package
- And so much more!

- Unrivalled Flexibility
- Automatic Data Transfer
- Unlimited Metadata Trending
- CrtV™
- User-friendly UI
- Interactive Development Record
- Access anywhere
- Language Options
- Intuitive Data Views
- Statistical support by Quants
Regulatory Compliance

- Quantics Biostatistics – bioassay consultancy for more than 20 years
- Director of Statistics sits on USP

- Membership Schemes
  - GLP (7 Years)
  - ISO9001:2015 (11 Years)

- Other Schemes
  - GCP
  - GMP
  - 21 CFR pt11
  - ICH
Accessing QuBAS
Or…
QuBAS Modes

Development Room

- Once you input data, you can design and re-design your method in the way that suits you best, using all of the tools QuBAS has available.
- Input data
- Data, Plate, Map: Create/Edit
- Analyse data:
- Examine data
- Define analysis options
- Auto-summary with every change
- Assign labels
- Automatically update parameters
- Notes

Routine Room

- 2-stage electronic sign-off
- Version control
- Method configuration file
- Regulated package
- Final version

GMP & 21 CFR pt11 Compliant
Data Input & Plugins

- Import any delimited text file e.g. .csv
- Other file formats (e.g. .xml, .xls) can be pre-processed by plug-ins
- Custom plug-ins can be built to suit individual customer needs
Auto-Import/Export
Continuous real-time Validation
Unique to QuBAS
Derived from the aerospace industry
- “Fly-by-wire” aircraft require 100% QC in real-time for reliability
- Use redundant systems and cross-check readings
CrtV™: Diverse Self Checking Pairs

1. Data Imported
2. R Analysis
3. C++ Analysis
4. R Compares with C++
5. C++ Compares with R
6. Results Checked
7. Mismatch: Report Error
8. All match: Produce Report
### CrtV™: Results

<table>
<thead>
<tr>
<th>Process</th>
<th>Result</th>
<th>Date/time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validation of installation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R install check</td>
<td>PASS</td>
<td>26-November-2020 15:33</td>
</tr>
<tr>
<td>App install check</td>
<td>PASS</td>
<td>26-November-2020 15:33</td>
</tr>
<tr>
<td>Engine install check</td>
<td>PASS</td>
<td>26-November-2020 15:33</td>
</tr>
<tr>
<td>Licence check</td>
<td>PASS</td>
<td>26-November-2020 15:33</td>
</tr>
<tr>
<td><strong>DSCPP Processes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>input XML validation</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
<tr>
<td>Parsing report ID</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
<tr>
<td>Parsing configuration file</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
<tr>
<td>Parsing statistical model</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
<tr>
<td>Parsing branch B configuration</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
<tr>
<td>Analysis (branch A)</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
<tr>
<td>Output validation for branch A</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
<tr>
<td>Analysis (branch B)</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
<tr>
<td>Output validation for branch B</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
<tr>
<td>Check results from both branches</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
<tr>
<td>Generate report from branch A</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
<tr>
<td>Generate report from branch B</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
<tr>
<td>Check that both reports are identical</td>
<td>PASS</td>
<td>03-December-2020 07:46 UTC</td>
</tr>
</tbody>
</table>

### Validation Results

- This is a routine analysis: **TRUE**
- Audit trail is complete: **PASS**
- All systems, file operation and analysis validation checks: **PASS**
- Results 100% QC check: **PASS**
- Reports text 100% QC check: **PASS**

This report is valid for use in GxP systems
Unique Features

- **All-in-one package**
  - Supports every stage of bioassay workflow – from development to GMP – as standard

- **User-friendly and intuitive**
  - No formulae or programming – less training!

- **Automatic Metadata Trending**
  - Use monitoring room to isolate assay parameters and metadata for further investigation