## Response document for MHRA consultation on the application of Analytical Quality by Design concepts to pharmacopoeial standards for medicines

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| About YouName: |
| Position: |
| Organisation: |
| Email: |
| Familiarity with AQbD concepts:None  Awareness Understanding Knowledge Expertise |
| Please indicate if you are responding to this consultation as an individual or on behalf of an organisationIndividual  Organisation  |
| About your OrganisationType:** Generics** – *a pharmaceuticals manufacturer of any size with most of its sales from generic drug products* **Large Pharma** – *a pharmaceuticals firm with annual sales of more than $2bn, and which develops and manufactures patented drug products as its primary activity* **Small/ Medium Pharma** – *a pharmaceuticals firm with less than $2bn in sales, and which develops and manufactures patented drug products as its primary activity* **Supplier** – *a supplier of services, materials or equipment to the pharmaceutical industry (includes testing companies, consultancies, raw materials suppliers)***Government** –  *OMCL* *Regulator* *Other* **Public Health** – *hospitals and medical clinics* **Academia** – *universities and colleges* **Other (Please state)** –  |
| Focus: *Please indicate your organisations focus on small and large molecules using the scale below. 3 indicates an equal focus on small and large molecules.***Small** 1 2 3 4 5 **Large** |
| Location (country):Head office:­­­­­­­­­­­­­­­­­­­­ Your site: |
| Organisation Size:1-5  6-50  51-250  250-1000 1001-9999 10,000+  |
| 1. What do you see as the greatest opportunities and challenges affecting the quality of medicines in the next 5 years? |
| 2. How can AQbD concepts ensure methods are fit for purpose and how can they enable innovation? How are AQbD concepts utilised within your organisation? |
| 3. Please rank examples 1 – 5 in order of preference for presentation in the pharmacopoeia (1 is best). What advantages and disadvantages do you see in presenting AQbD information in the different examples? Rank 1 – ExampleRank 2 – ExampleRank 3 – ExampleRank 4 – ExampleRank 5 – Example |
| 4. What other options for the application of AQbD concepts to pharmacopoeial standards and presentation of the resulting information in the pharmacopoeia should we consider? |
| 5. How can we work with you and your organisation to further develop our thinking on the application of AQbD concepts to pharmacopoeial standards? |
| 6. Do you have any other comments regarding the application of AQbD concepts to pharmacopoeial standards? |
| 7. Would you be happy for the MHRA to contact you in order to discuss your responses in further detail?Yes  No  |
| 8. The MHRA may publish consultation responses. Do you want your response to remain confidential?Yes  Partially\*  No  \*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete. |

Responses can be continued onto a separate page if required. This form should be returned by email (AQbDStds@mhra.gov.uk) to arrive by **31 August 2019.** Contributions received after that date cannot be included in the exercise.