

## European QP Association Survey Results

Frequently, QPs (and companies) have difficulties in keeping the manufacturing specifications and the marketing authorizations in synch for actively changing products globally with different product specifications and approval timelines. Moreover, an additional challenge comes in with the distribution sites and the processes used by the distribution sites to determine which product is currently approved for shipment to a particular country. For that reason we set up the following brief questionnaire to find out whether you or your company's regulatory department have some system in place ensuring that the actual status filings or changes of products is monitored and in compliance? We would very much appreciate it if you took two minutes to answer and return the questionnaire.

### Chairman

Dr. Bernd Renger  
Director Quality Control  
Vetter Pharma-Fertigung GmbH & Co. KG  
Germany

### Advisory Board Members

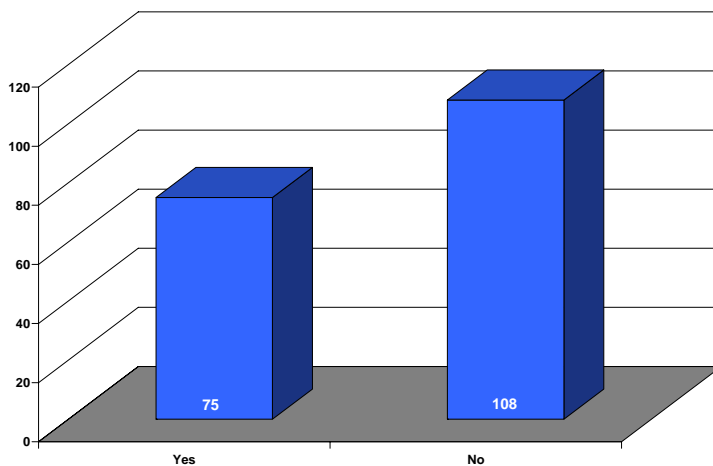
Richard Bonner  
Qualified Person  
UK

Dr. Christopher Burgess  
Burgess Consultancy  
UK

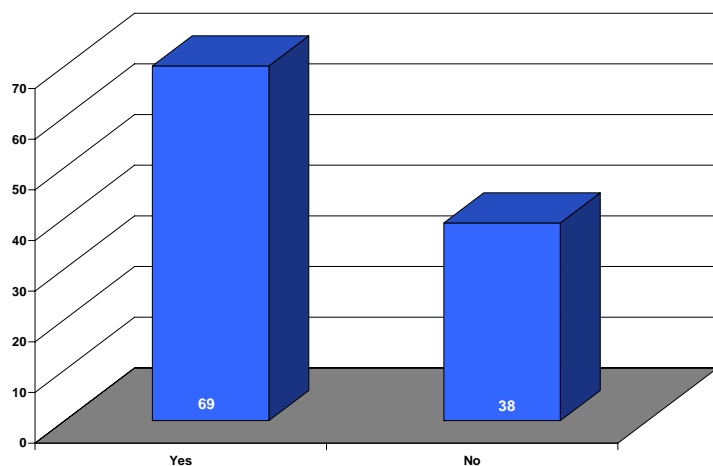
John Taylor  
Medicines & Healthcare Products  
Regulatory Agency  
UK

Rudolf Völler  
GMP Inspectorate Darmstadt  
Germany

### 1. Do you have access to an electronic or paper based system that allows you to check the actual status of filings and changes on a global basis of all the products you certify?

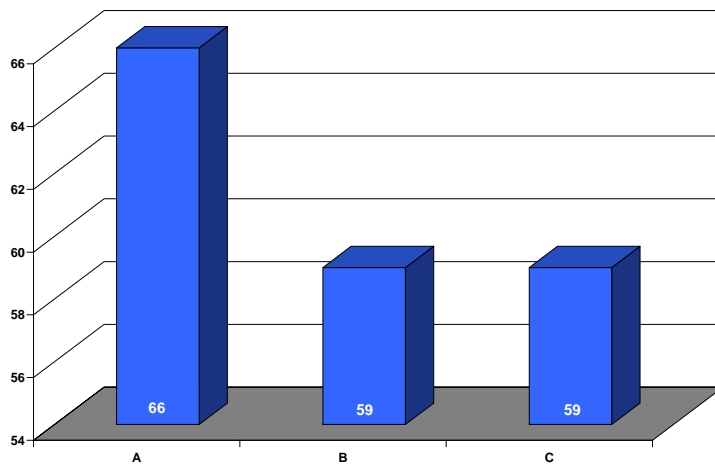


### 1.1 If No: does your regulatory department have in place an electronic or paper based system that allows to check the actual status of filings and changes on a global basis of all the products of your company?



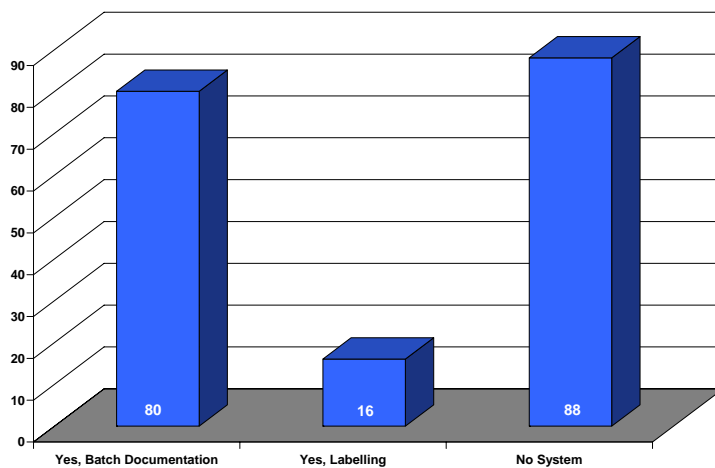
**2. How do you ensure that you only certify batches that have been manufactured according to the actual marketing authorizations?**

- a) Regular check of manufacturing and testing documents together with regulatory department.
- b) Active participation of QP in change control board.
- c) The QP is required to sign-off on any changes to the registered specification.



**3. Do you have a system in place that released products sitting in distribution centres can be checked for compliance with latest regulatory changes prior to shipment to a particular country?**

- a) Yes, based on batch documentation
- b) Yes, via labelling (codes on packaging)
- c) No system.



**Chairman**

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