Classification of Batch Recalls for Quality Defects

**Class 1:** Defects, which are potentially life-threatening or could cause serious risk to health.

Examples:

1.1: Wrong product (label and contents are different products).
1.2: Correct product but wrong strength, with serious medical consequences.
1.3: Microbial contamination of sterile injectable or ophthalmic product.
1.4: Chemical contamination with serious medical consequences.
1.5: Mix up of some products (“rogues”) with more than one container involved.
1.6: Wrong active ingredient in a multi-component product with serious medical consequences.

**Class 2:** Defects, which could cause illness or mistreatment but are not Class 1.

Examples:

2.1: Mislabelling: e.g. wrong or missing text or figures.
2.2: Missing or incorrect information - leaflets or inserts.
2.3: Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences.
2.4: Chemical/physical contamination (significant impurities, cross-contamination, particulates).
2.5: Mix up of products in containers (“rogues”).
2.6: Non-compliance with specification (e.g. assay, stability, fill/weight).
2.7: Insecure closure with serious medical consequences (e.g. cytotoxics, child-resistant containers, potent products).

**Class 3:** Defects which may not pose a significant hazard to health but where a recall has been initiated (perhaps not required by the competent authority) for other reasons, but are not Class 1 or 2.

Examples:

3.1: Faulty packaging: e.g. wrong or missing batch number or expiry date.
3.2: Faulty closure
3.3: Contamination
   - microbial spoilage
   - dirt or detritus
   - particulate matter