



Medicines & Healthcare products  
Regulatory Agency

# Decision tree for navigating nanotechnology-based products for medical application

February 2025



Is the product classified as a medicinal product or a medical device?

Medicinal product \*

Medical device #

Is the product a 'copy' / nano-similar / biosimilar of an authorised medicinal product?

Y

N

Is it a biological product?

Y

N

Is it liposomal doxorubicin or amphotericin product?

Y

N

Follow the biosimilar guideline <sup>(1)</sup> and consider the CQAs for the 'nano' component

Follow the reflection paper on liposomal products <sup>(2)</sup>

Check legal basis before submission <sup>(5)</sup>

Bioequivalence study is required <sup>(3-4)</sup> and all other ICH quality guidelines should be applied, where relevant

Determine the type of biological product and follow the relevant ICH or MHRA guidance e.g. ATMP (including GTMP, somatic cell therapy or tissue engineered product) and vaccine

Is it a biological product?

Y

N

DS = Drug substance  
DP = Drug product

Consider New Active Substance (NAS) status

Guidelines related to chemical drug substance and drug product would be required

Consider New Active Substance (NAS) status

ICH Q5A  
ICH Q5B  
ICH Q5D  
ICH Q6B  
ICH Q5C  
ICH Q7

ICH Q5A  
ICH Q6B  
ICH Q5C  
ICH Q8(R2)

ICH Q1A (R2)  
ICH Q2 (R1)  
ICH Q3A (R2)  
ICH Q3B (R2)  
ICH Q3C (R6)  
ICH Q3D  
ICH Q6A  
ICH Q8 (R)

ICH Q9  
ICH Q10  
ICH Q11  
ICH Q13  
ICH M7  
QP declaration  
BP/EP

## References

Note the ICH guidelines recommended for reference above are not meant to be exhaustive. Additional considerations should be made following evaluation of the individual products.

\* Reference to Human Medicines Regulation 2012 should be made for the definition of a Medicinal Product.

# Reference to Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) should be made for the definition of a Medical Device. Consideration for medical devices is outside the scope of this decision tree.

1. Guidance on the licensing of biosimilar products (<https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products>)
2. Reflection paper on the data requirements for intravenous liposomal products developed with reference to an innovator liposomal product (EMA/CHMP/806058/2009/Rev. 02)
3. Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/ Corr \*\*)
4. Comparator products in Bioequivalence/Therapeutic Equivalence studies (<https://www.gov.uk/guidance/comparator-products-in-bioequivalencetherapeutic-equivalence-studies>)
5. Types of application (legal basis) (<https://www.gov.uk/guidance/types-of-application-legal-basis>)

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