Introduction: Assessing immunogenicity of adaptive immune responses via *in vitro* assays

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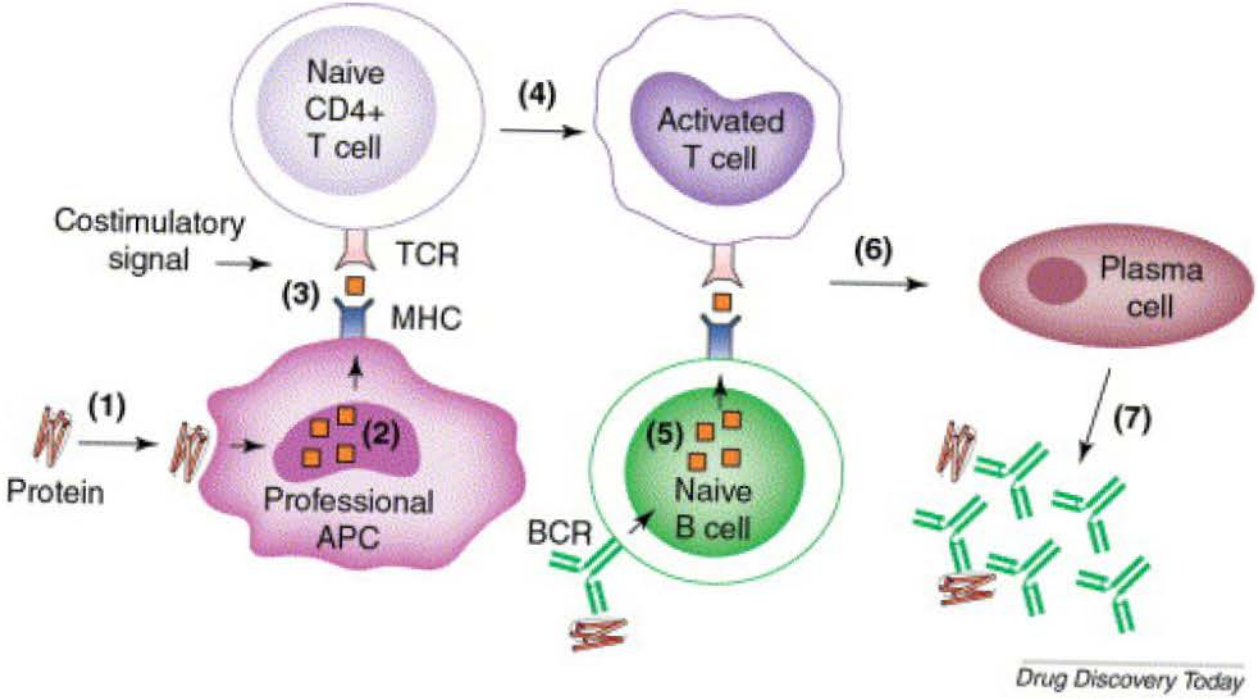
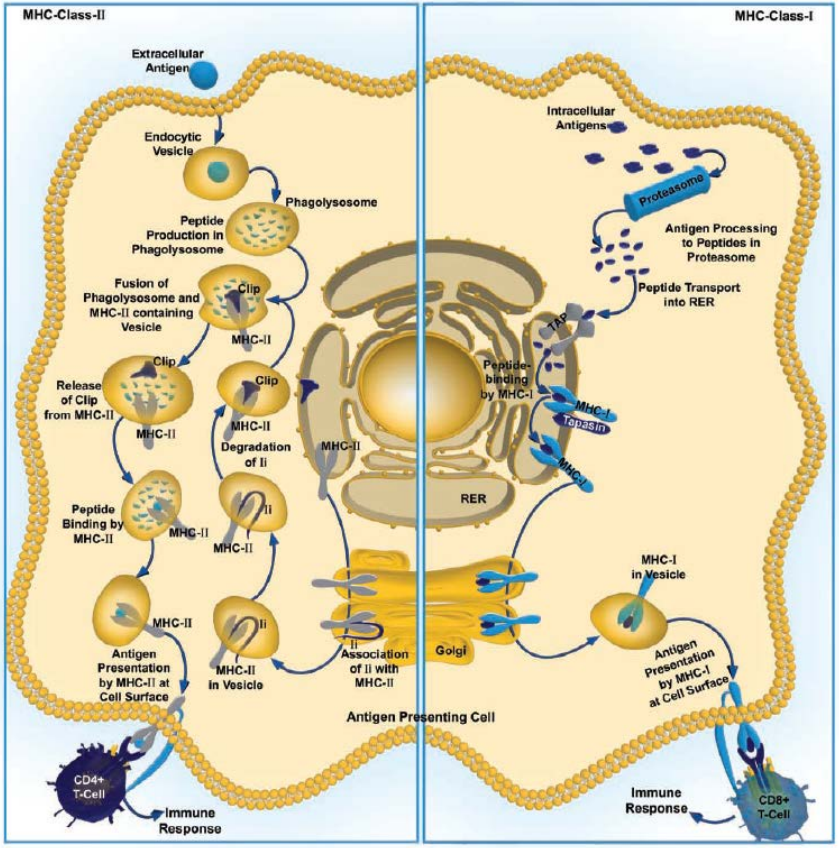
This presentation reflects the views of the author and should not be construed to represent FDA's official views or policies.

Development of anti-drug antibodies



Chirino AJ et al, DDT, Vol 9, No 2, Jan 2004

Peptide recognition and processing



Classical antigen processing and presentation:

- Peptides are processed
- Typically 15-20 amino acids following processing
- Binding to MHCII for presentation to T-cells

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Non-classical peptide presentation

- Many ‘non-classical’ pathways exist
- Permits non-peptides, glyco-peptides and peptides that do not undergo classical processing to be presented
- May result in immunogenicity to peptides not predicted via *in silico* methods

Questions…

- What assay methodology(ies) is/are useful?
- How many T cells should be assessed?
- Role of HLA?
- Assay readout(s)?
- Appropriate positive/negative controls?

Introduction to Session 3

- **Talk 1**: Dr. Campbell Bunce, Abzena

"Ex vivo immunogenicity assays – landscape and limitations"

- **Talk 2**: Dr. Sofie Pattijn, ImmunXpert

"T cell immunogenicty assays: time for harmonisation and standardisation"

- **Talk 3**: Dr. Noel Smith, Lonza

"Human PBMC-based assays for the immunogenicity risk assessment of therapeutic peptides"


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