

# European Bioanalysis Forum

## Welcome and introduction

2<sup>nd</sup> EBF Focus Meeting – Large meets Small

21-22 June 2011, Brussels, Belgium



## 2<sup>nd</sup> Focus Meeting

### "Large meets Small"

Connecting strategies on analyzing large molecules with small molecule technologies

- Review of MS platforms in peptide/protein/large molecule analysis
- Regulatory challenges in large molecule analysis by LC-MS
- Technical challenges and solutions in sample preparation and analysis of large molecules by LC-MS in biofluids
- Proteins in the MIST

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Welcome to you all

A big Thank you to our sponsors



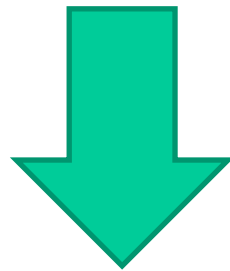
A big Thank you to the OC

- Begona
- Berthold
- Christina
- Peter
- Philip
- Silke

# Why this meeting?

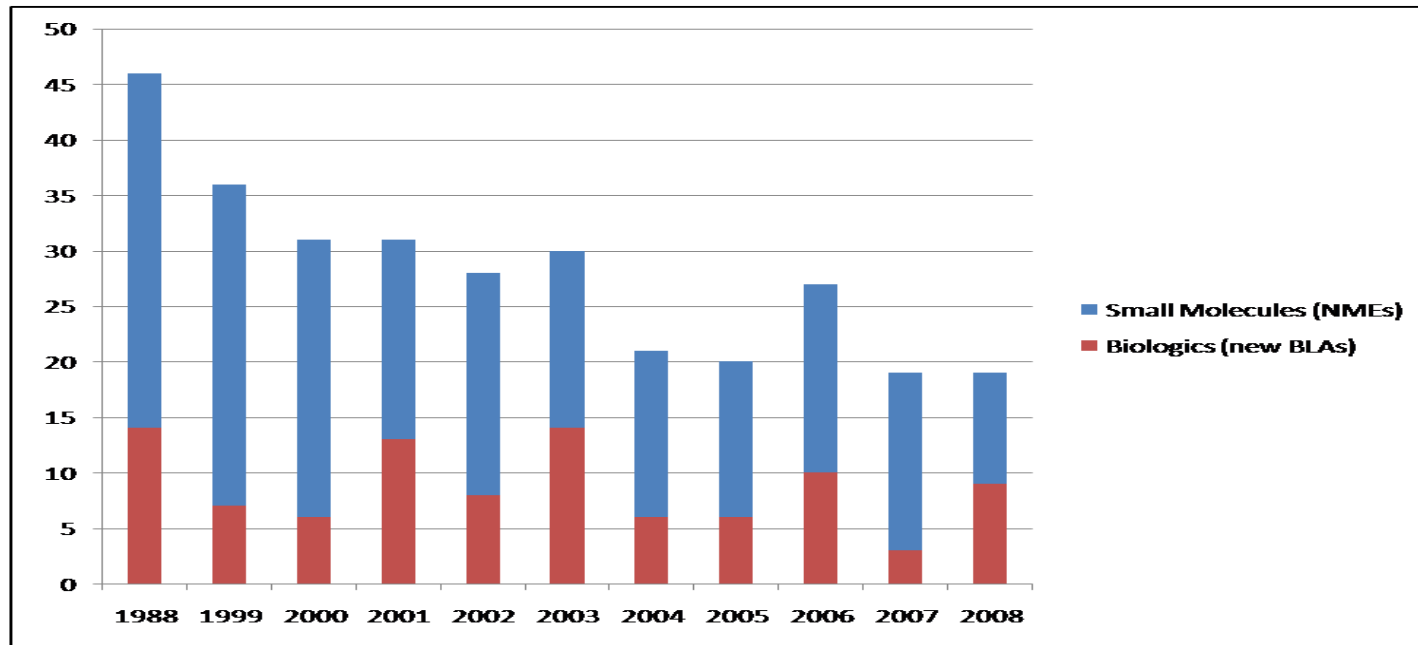
Peptide/protein portfolios rapidly growing

Peptide/protein LCMS opportunities  
exponentially growing



Now is the time to reflect and connect !

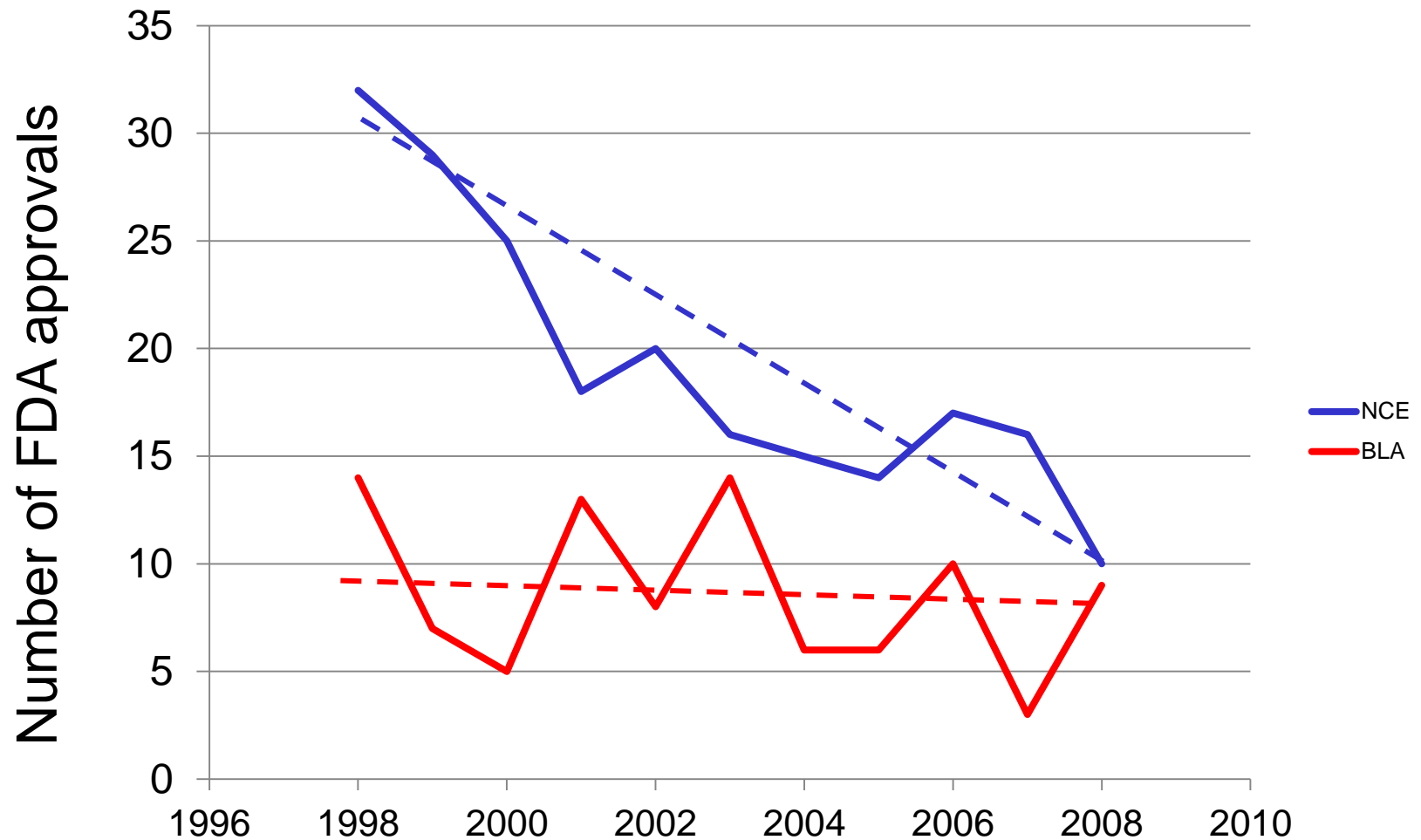
## NCE versus Biologics – FDA approvals



	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Small Molecules (NMEs)	32	29	25	18	20	16	15	14	17	16	10
Biologics (new BLAs)	14	7	6	13	8	14	6	6	10	3	9
Total	46	36	31	31	28	30	21	20	27	19	19
Avg Total '88-'03 vs '04-'08	34						21				
Percent	30.4%	19.4%	19.4%	41.9%	28.6%	46.7%	28.6%	30.0%	37.0%	15.8%	47.4%
Avg % Biologics '88-'03 vs '04-'08	31.1%						31.8%				
Biologics (Mabs and Ther. Proteins)*	8	2	6	1	2	5	3				

Source: M. R. Trusheim, M. L. Aitken, and E. R. Berndt, "Characterizing Markets for Biopharmaceutical Innovations: Do Biologics Differ from Small Molecules?" Forum for Health Economics & Policy, 2010 13, issue 1, article 4

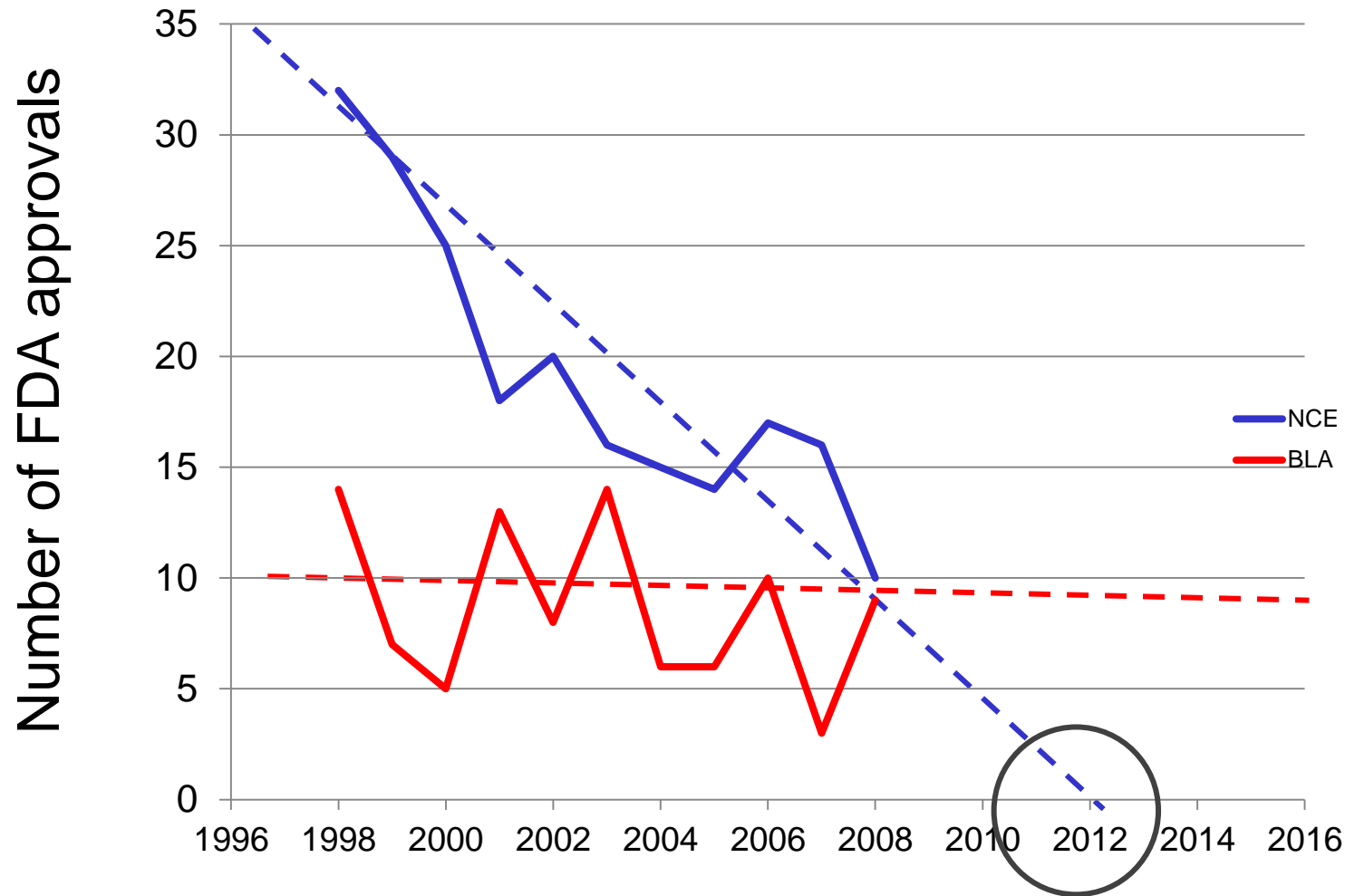
# NCE versus Biologics – FDA approvals



Source: M. R. Trusheim, M. L. Aitken, and E. R. Berndt, "Characterizing Markets for Biopharmaceutical Innovations: Do Biologics Differ from Small Molecules?" Forum for Health Economics & Policy, 2010 13, issue 1, article 4

# NCE versus Biologics – FDA approvals

let's hope the trend changes, if not, in 2012 NCE are history



Or for NCE, this will be true after all....

2012



# What about peptides?

## Average frequency of peptides entering clinical trials

- 1970-1980: 1 per year approx.
- 1980-1990: 5 per year approx.
- 1990-2000: 10 per year approx.
- 2000-2010: 20 per year approx.

## Sales and FDA-approvals (as per 2010):

- 60 peptide drugs approved
- annual sales = approximately 13 billion US\$. (or 1.5% of all drug product sales)
- continuous annual growth rate (CAGR) between 7.5% and 10%.

## Near future:

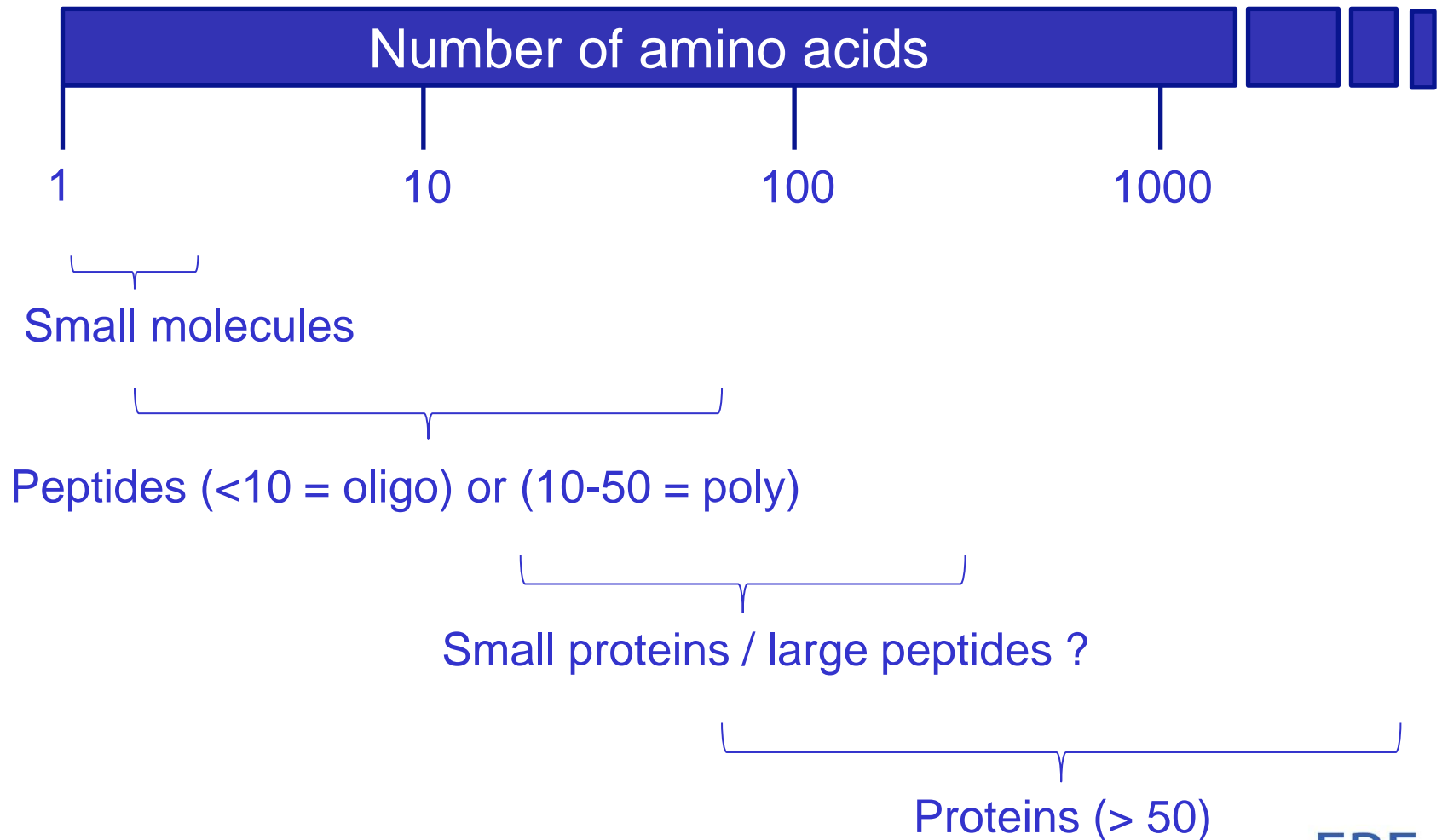
- about 140 peptide candidates in the clinic
- (best guess) about another 500 – 600 in pre-clinical development.

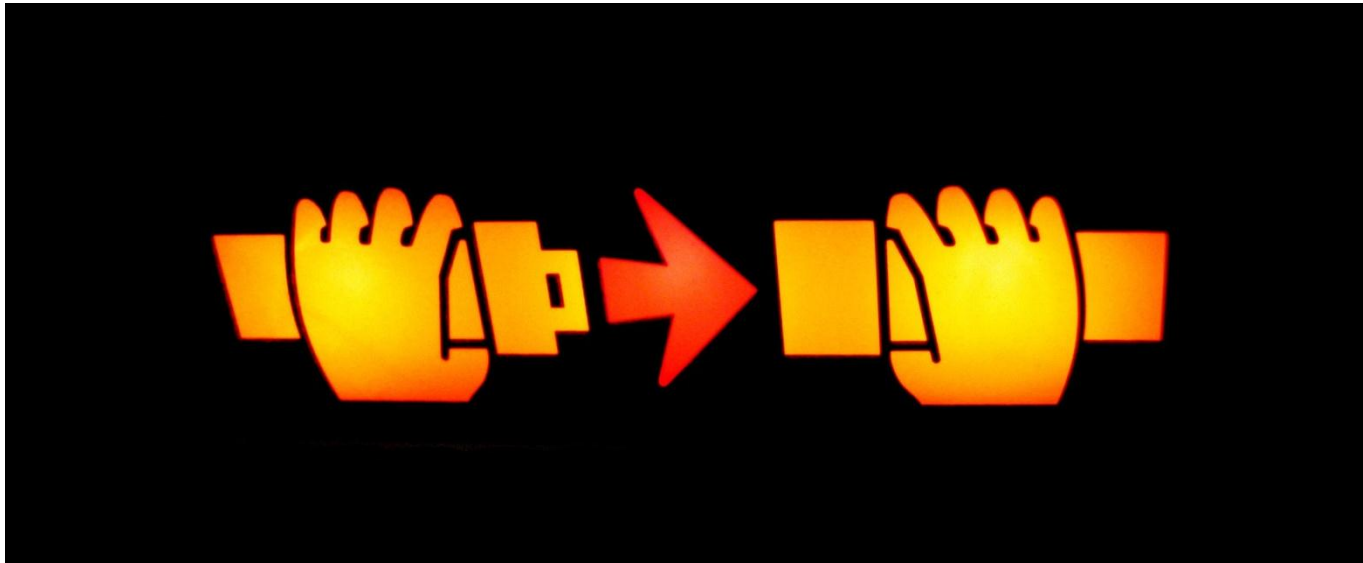
Source: The Future of Peptide Development in the Pharmaceutical Industry  
Rodney Lax, Ph.D., Senior Director of Business Development North America, PolyPeptide Group  
<http://www.peptidetherapeutics.org/peptide-therapeutics-foundation.html>



- Over the last 3-5 years rapid and exciting developments of high-end MS equipment
- At same pace, exponential growth of applications in the (quantitative) bioanalytical environment
  - Biomarkers
  - Therapeutic Peptides – NBEs
- Cross fertilization of LBA and MS/MS

# Peptides versus Proteins: semantics and confusion ?





...and enjoy the meeting