

## PolymerForum

# The PolymerForum IPAC-RS Materials Forum 13-14Sep2009

Taina Tjäder

AstraZeneca

Bayer HealthCare  
Bayer Schering Pharma

Boehringer  
Ingelheim

gsk  
GlaxoSmithKline

NOVARTIS

Pfizer

sanofi aventis

TEVA

VECTURA

## Timeline and Achievements of PolymerForum

PolymerForum

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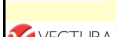
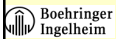
Initiated in June 2003. With membership comprising;  
AstraZeneca, BBraun, GSK, BI, Novartis, Sanofi-Aventis, Vectura

Meetings held through 2004 leading to the November 2004  
Symposium presenting to Supply Base.

By spring 2009 altogether 14 companies have joined the forum;  
AstraZeneca, Bayer Schering Pharma, Boehringer Ingelheim, Glaxo  
SmithKline, Johnson&Johnson, 3M, Novartis, Orion Pharma, Pfizer,  
Roche, Sanofi-Aventis, Schering-Plough, Teva, Vectura

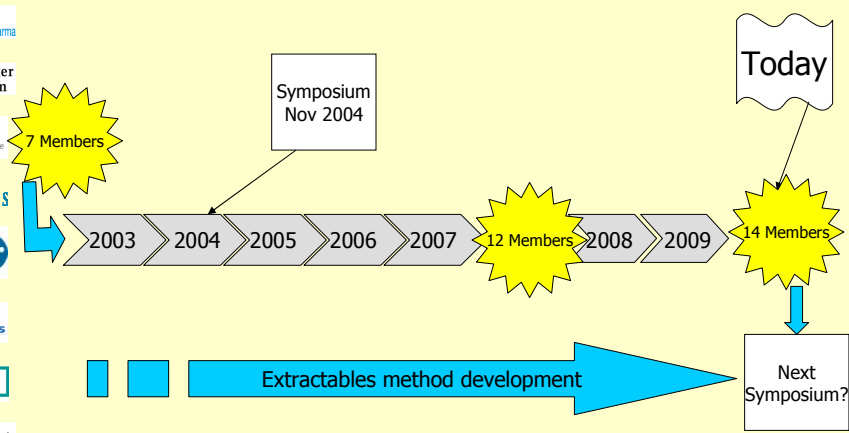
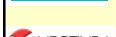
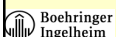
A world-wide consortium covering both European and US based  
companies

## Meeting History

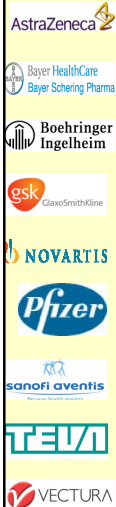


- June 2003 – GSK, London, UK
- Feb 2004 – BI, Ingelheim, D
- April 2004 – Novartis, Basel, CH
- June 2004 – AstraZeneca, S
- Nov 2004 – Symposium, Frankfurt, D
- Feb 2005 – Sanofi-Aventis, Manchester, UK
- June 2005 – GSK, London, UK
- October 2005 – Vectura, Windsor, UK
- March 2006 – Bayer Schering, Turku, Fi
- October 2006 – Teva, Waterford, Ir
- March 2007 – Pfizer, New Jersey, USA
- October 2007 – BI, Bad Kreuznach, D
- June 2008 – Astra Zeneca, S
- June 2009 – Novartis, Basel CH
- 2010 – Roche, CH

## Timeline



## Obligations of Polymer Forum members



No commercial discussions

No disclosure of intellectual properties

No breaches of confidentiality



## Main activities and objectives



Annual meetings and continuous dialogue in between

Polymer Suppliers present their Pharma strategies to members during meetings

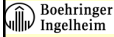
Internet website ([http:// www.polymerforum.com](http://www.polymerforum.com))

Strategic group

The Polymer Forum's strategic intent is to improve and standardise the Polymer Supplier's approach to the marketing and supply of Medical grade polymers;

- Provide guidance on pharmaceutical requirements of polymers used in medical devices and pharmaceutical packaging
- Define minimum needs for international pharmaceutical market
- Offer open communication

## Main activities and objectives



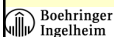
Increased security of supply by giving 3 years notification of change.

Last-call option previous to production discontinuation, in order to guarantee supply to patients, to be negotiated.

Improved understanding of Pharma companies' requirements.

Evidence of Success from Supplier engagement and presentations received

## Main activities and objectives



Technical group

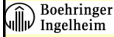
Target :

To develop a common analytical method(s) for extractables testing for incoming polymers.

Reasons:

- What is in may come out => Potential leachables should be known (safety concern)
- Regulatory requirements
  - differ depending on the route of administration
- Routine extractables testing: batch to batch consistency in composition and purity
- The production batches should always provide extractables profile inside registered and toxicologically tested composition

## Main activities and objectives



- Extraction profile depends on extraction conditions and technique => Different practices among pharma companies  
=> diverse extraction requests to plastic industry

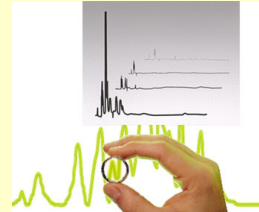
### Main focus in the technical group

to develop a generic, broadly accepted method(s) for plastic industry to monitor extractables from medical products

First initiatives: polyolefines followed by ABS/MABS

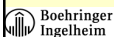
Outside partners used for methodology development

Polymer suppliers supporting by giving model resins and testing with their analytical methods



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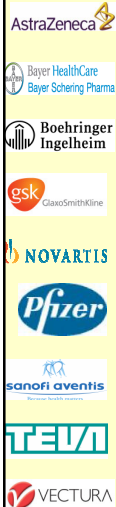
## Effects of polymer forum work; examples



- A constant interest of polymer suppliers for dialogue with Polymer Forum
  - Supplier presentations during yearly meetings
  - Direct contacts taken to Polymer Forum
- Lessons learned
  - Companies with medical policies far from the needs of pharmaceutical industry have been open for proposals and discussion
  - Some of those have revised their views to better meet pharma requirements
- An open dialogue when changes planned
  - A joint interest for well-controlled changes
    - Raw material, process, compositional or site changes
    - Discontinuation of commercial medical grades
  - Pharma needs/views valued
  - Polymer suppliers have a path via Polymer Forum to get practical advice about special medical requirements

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## Effects of polymer forum work; examples



- One voice – higher impact
  - Polymer forum has provided guidance how to manage and communicate planned discontinuation / change processes by
    - negotiating face to face with the supplier to guarantee
      - » a controlled rundown with guaranteed transition period to allow us to validate new material grades for our products
      - » required minimum testing for the material in case of changes
    - by bringing up the concerns of pharmaceutical industry towards planned actions
- Understanding of consequences has increased
  - A minor change in a polymer manufacturing chain might cause
    - Major troubles to pharmaceutical industry
    - Cause a lot of testing and clarifications and even regulatory variations
    - To verify a change might require years' investigations
  - Importance to inform in advance

## Technical group: Extractables Method Development



### Aim:

- The Polymer Forum wishes to develop generic method(s) for monitoring extractables from plastics for pharmaceutical products and devices for use by plastic suppliers.

### Purpose:

- Provide to suppliers a method to monitor consistency in composition of the final plastic including control of unintended changes at the manufacturer

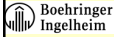
### Long term vision:

- Provide to the plastic industry a range of harmonized methods for monitoring extractables from a broad range of plastic materials to design and maintain high quality products for our patients

### Benefits:

- Partnership between Pharma industry and their suppliers based on:
  - Common understanding on the needs and requirements of the pharma industry
  - Harmonized approach and common standard
  - Continued quality through periodic verification of composition

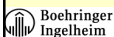
## Status: Polyolefine methodology



- An external partner responsible for developing a method for a model high density polyethylene
  - 2 extraction techniques compared and various chromatographic methods
  - 3 batches
  - Extraction conditions' optimisation completed
- Results to be compared with our own in house methods
- Round-robin testing among member companies
- Development work to be continued with other polyolefines with different additive packages to check the suitability of the method
  - 18 polymer samples received
- After being finalized the method would be available for plastic industry as a commonly accepted (by many pharmaceutical companies), harmonized method to control the effects of changes on the material composition.

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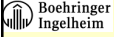
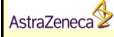
## Status: other materials



- Preliminary work started with external partner for ABS/MABS materials
  - Preliminary checks done and continuation to be agreed in near future
- Other materials: no actions taken so far

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## PolymerForum continuation.....



Regular meetings at a location easily accessible to all

- Supplier presentations => Continuous dialogue with resin producers
- Member companies discuss current and future activities

Presentations given time to time in various forums to achieve visibility among polymer suppliers

Finalize extractables method development for polyolefines and decide on continuation

In the near future plans to host a next symposium for polymer suppliers to give an update of Polymer Forum work and to create a channel to joint discussions between pharmaceutical industry and bulk polymer suppliers