



**VITEK 2**  
— *compact*

**Gold Standard for Phenotypic Identification**

# The Technology

## Presented to GSK in 2005 as a “Completely New System”

- **New instrument:**
  - vacuum filler, cassette loader, sealer, reader carousel and waste container included in one compact instrument
  - PC
  - LCD Flat Screen Display
  - DENSICHEK
- **New menu of test kits**
- **New Software:**
  - 21 CFR Part 11 Features



# GSK PRELIMINARY EVALUATION OF THE TECHNOLOGY

## Objectives

1. To evaluate the VITEK® 2 Compact automated identification system
2. Analysis of the VITEK® 2 Compact performance characteristics against the Omnilog and Microstation identification systems

## To accomplish this:

Approximately 180 environmental isolates from the Barnard Castle Site were tested simultaneously on the VITEK® 2 Compact, Omnilog and Microstation.



# GSK PRELIMINARY EVALUATION OF THE TECHNOLOGY con't

## Isolates

### Where did the isolates come from?

Study isolates were collected over a 3 month period from the routine samples submitted to the identification department.

### What types of isolates were encompassed in the study?

The study covered:

1. Gram positive cocci
2. Gram positive sporing bacilli
3. Gram negative bacilli (enteric, non-enteric)
4. Yeast (VITEK<sup>®</sup> 2 Compact and Microstation only)

In total approx. 40 different species were tested.

# **GSK PRELIMINARY EVALUATION OF THE TECHNOLOGY con't**

## **The Systems**

**The VITEK<sup>®</sup> 2 Compact and the Omnilog are automated systems whereas the Microstation is semi-automated.**

**The three systems are based on phenotypic identification.**

**The VITEK<sup>®</sup> 2 compact uses biochemical methods, carbon source utilisation and enzymatic activities and employs up to 64 different wells.**

**The Omnilog and Microstation systems rely on carbon utilisation reactions and employ 95 carbon source utilisation tests.**

# GSK PRELIMINARY EVALUATION OF THE TECHNOLOGY con't

## Isolate Preparation – VITEK® 2 Compact & Omnilog Plus



Suspension is prepared



Read bar code on plate



Enter Sample Identifier



Sample placed into vacuum chamber



Then transferred to the reader



Cards discarded into bin



Suspension is prepared



Suspension is poured into reservoir



Suspension is manually pipetted into the microplate



Enter Sample Identifier



Place Microplates into Reader



**When samples are finished remove microplates**

# GSK PRELIMINARY EVALUATION OF THE TECHNOLOGY con't

## Results – Definitions (VITEK® 2 Compact)

### Single Choice Identification

- Includes single species identifications and slashline identifications

### Low discrimination

- Indicates that biochemical results for an organism closely resemble the species pattern of two or more closely related organisms

### No Identification

- No form of identification obtained

# GSK PRELIMINARY EVALUATION OF THE TECHNOLOGY con't

## Results – Definitions (Omnilog & Microstation)

### Single Choice Identification

- Includes single species identifications and genus identifications

### TOP 10

- No identification is given but there is a top 10 rank of isolates to aid in the identification of the test organism

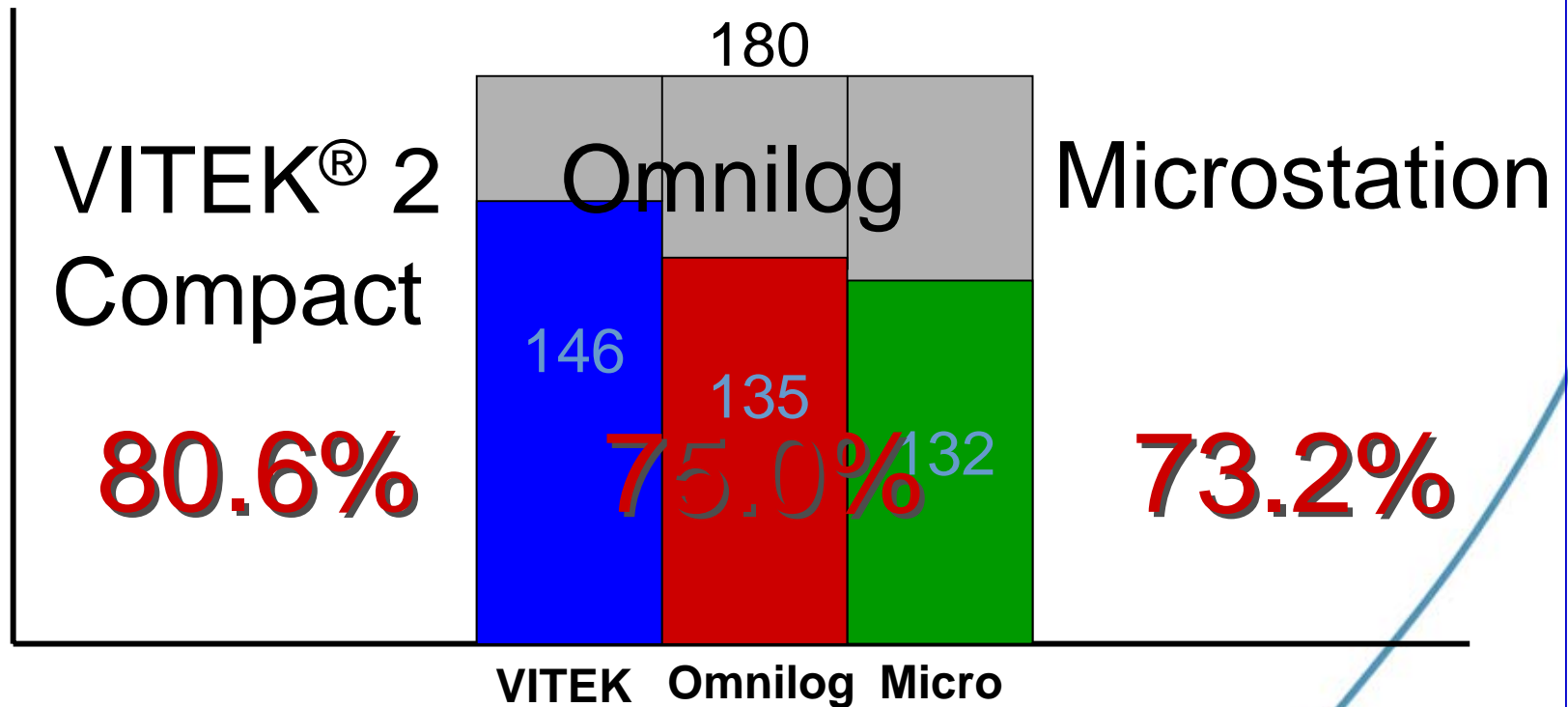
### No Identification

- No form of identification obtained



# GSK PRELIMINARY EVALUATION OF THE TECHNOLOGY con't

## Summary – Total Single Choice Identification



# GSK PRELIMINARY EVALUATION OF THE TECHNOLOGY con't

## Operator Observations

- Card set-up easy and quick
- 3ml saline required
- Low density solution
- Rapid results <10hrs
- Standard laboratory media required
- User interface good

## Conclusion

**The results of this study show that the VITEK® 2 Compact was able to satisfactorily identify the majority of the routine microbiological isolates encountered in a pharmaceutical manufacturing environment**

# VITEK 2 COMPACT AS A GLOBAL PROJECT FOR GSK

## GSK global project

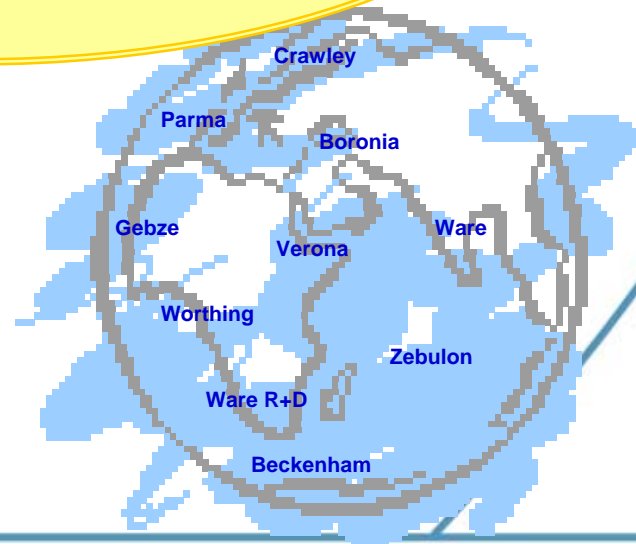
- ❖ Speciation system of choice for GSK
- ❖ Multi-site validation working party established
- ❖ Barnard Castle as lead site
- ❖ 10 further GSK sites involved
- ❖ Global VMP and URS issued
- ❖ Close liaison with supplier for standard validation
- ❖ Involvement of central Procurement

Optimise capital purchase costs

Reduced consumables costs

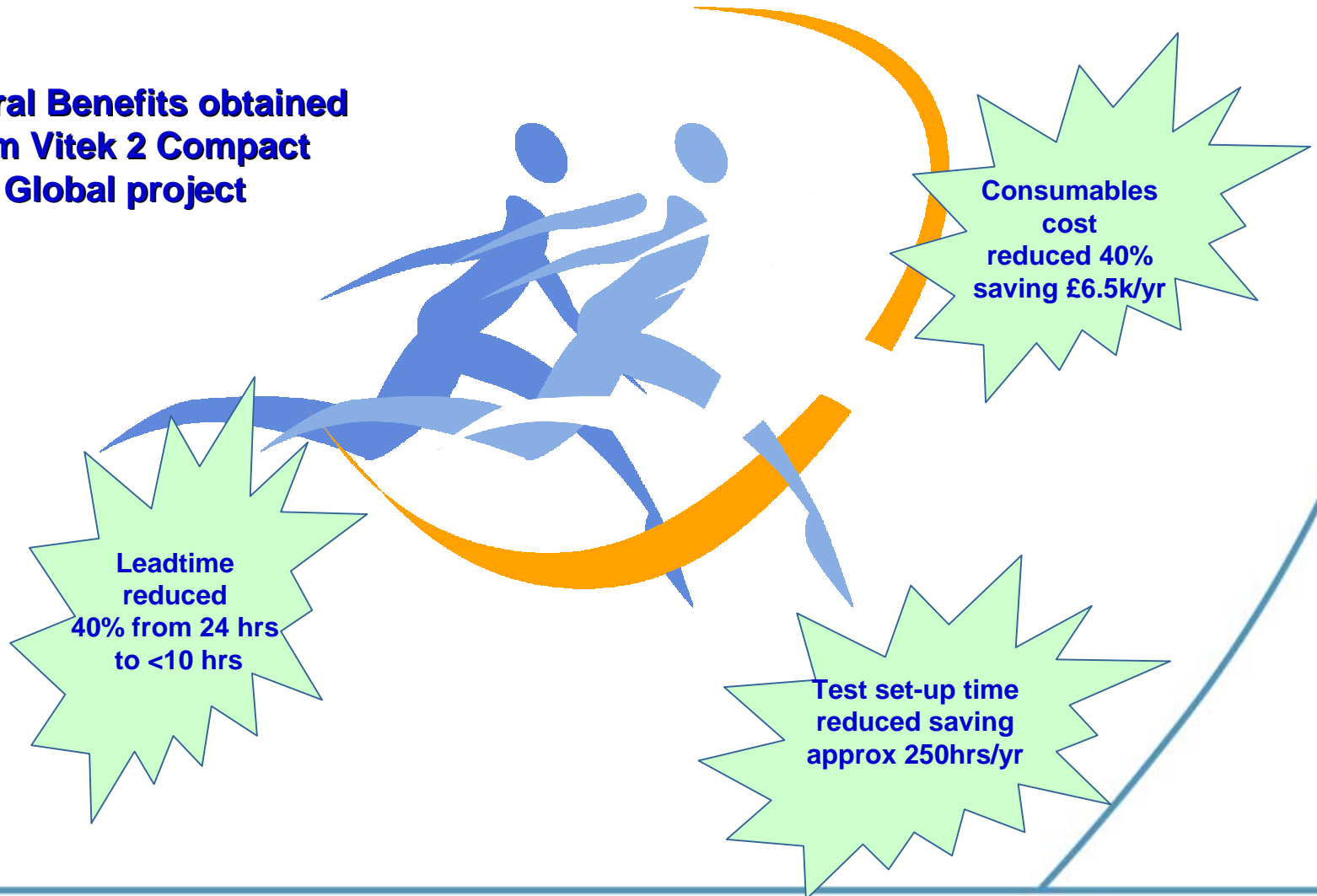
Rationalise/reduce validation at receiver sites

Consolidated standard network approach



# VITEK 2 COMPACT AS A GLOBAL PROJECT FOR GSK con't

## General Benefits obtained from Vitek 2 Compact Global project



# VITEK 2 COMPACT AS A GLOBAL PROJECT FOR GSK con't

## Global Project Phases and Time-Line

### PHASE 1

#### GLOBAL TEAM PLAN

- Global URS
- Global VMP
- Audit to BioMerieux
- Central Procurement Involvement

### PHASE 2

#### LEAD SITE ACTIVITIES

- Lead Site DQ
- BioMerieux Standard Validation Package
  - Lead Site IQ
  - Lead Site OQ
  - Lead Site PQ

### PHASE 3

#### LOCAL SITE ACTIVITIES

- BioMerieux Standard Validation Package
  - Local Site IQ
  - Local Site OQ
  - Local Site PQ

JAN – JUNE 2006

JULY – AUG 06

SEP – DEC 06

GLOBAL VALIDATION GROUP SUPPORT

# VITEK 2 COMPACT AS A GLOBAL PROJECT FOR GSK con't

## Lead Site Performance Qualification

### Reproducibility - 3 operators per organism singly

#### GN card

*Klebsiella oxytoca* ATCC 700324

*Enterobacter cloacae* ATCC 700323

*Stenotrophomonas maltophilia* ATCC 17666

#### GP card

*Streptococcus equi* ssp. *zooepidemicus* ATCC 43079

*Enterococcus casseliflavus* ATCC 700327

*Streptococcus thermophilus* ATCC 19258

#### YST card

*Trichosporon mucoides* ATCC 204094

*Candida glabrata* ATCC MYA-2950

*Candida lusitanae* ATCC 34449

#### BCL card

*Bacillus licheniformis* ATCC 12759

*Geobacillus stearothermophilus* ATCC 12978

*Paenibacillus macerans* ATCC 8509

### Repeatability - 1 operator repeating isolates 3 times with:

- Same sample card
- Different suspensions/Same density
- Same day

#### Choice of organisms based on:

- Objectionable organisms typically required to be absent in microbiological testing
- Representatives of genera or groups of commonly encountered environmental isolates
  - 4 Gram positive cocci.
  - 4 spore -forming bacilli.
  - 3 yeasts.
  - 1 Gram negative coccus.
  - 2 Gram negative cocco-bacilli.
  - 2 Enterobacteriaceae.
  - Six pseudomonads.

# VITEK 2 COMPACT AS A GLOBAL PROJECT FOR GSK con't

## Local Site Performance Qualification

- Based on the comprehensive lead site testing of the Vitek 2 System the amount of testing performed at each receiving site has been reduced.
- On site testing based on 4 ATCC organisms (representing each of the 4 biochemical cards) used by the Vitek 2 Compact. In addition each site will include a single site environmental organism as a minimum.

### Next Step:

- Future Validation of biochemical cards for *Corynebacterium* spp, *Neisseria* spp, .Anaerobes, *Campylobacter* spp and *Lactobacillus* spp.