Overview

• History of Balda Group
• Company structure Balda Group
• Locations Balda Healthcare
• Core technologies
• Quality
• Our spirit
• The markets

>> We improve peoples quality of life.
History of adaption to industrial cycles

• 1908  Foundation of Balda Company as a producer of cameras
• 1952  Establishment of precision injection molding as core process
• 1995  Entry into the mobile phone market
• 2000  Setting up of Balda Group / Technology Park in Germany
• 2002  Foundation of Balda Medical, Germany
• 2006  Entry into the Touch screen business
• 2012  Acquisition of two companies in the U.S. market
• 2013  Forming of the international Business Unit Balda Healthcare
• 2014  Setting up of a site for labor intensive assembly in Romania

More than 100 years of experience in innovative and international markets with permanent change and reinventing the business model.
Balda Group Structure

- **Locations:**

  Germany: Bad Oeynhausen

  USA: Anaheim
  Irvine
  Ontario
  Oceanside

- Balda Healthcare is one of the leading global manufacturers of OEM customized healthcare products made of plastics.
- We provide life cycle competence from product design, development, industrialisation, regulatory approvals, series production, global supply chain management up to continuous improvement programs.
- Our core technologies are multi-component precision injection moulding (clean room), automated system assembly, surface decoration as well as tool making.
- We are passionate, committed and excellent in operations.
Balda C. Brewer, Inc., USA

- **History:** Founded in 1966
- **Staff:** 500 employees
- **The sites:** Anaheim, Irvine, Oceanside, Ontario
- **Certificates:** ISO 13485, ISO 9001, TS 16949, UL Certification
- **Capacity:** 17.800 m² production space, including 1.000 m² class 8 clean room facilities
- **Market segments:** Healthcare, Eyewear, Automotive, Consumer Electronics
- **Managing Directors:** Misaki Gertz, Christoph Klaus, Vincent Lloyd Muir
Balda Medical GmbH & Co. KG, Germany

- **History:** Founded in 2002
- **Staff:** 200 employees
- **Site:** Bad Oeynhausen
- **Certificates:** DIN EN ISO 9001
  DIN EN ISO 13485
  DIN EN ISO 15378
  MDD 93 / 42 / EWG
  FDA-registered
  ISO 14001
  DIN EN ISO 50001
  BS OHSAS 18001
- **Capacity:** 14,000 m² production space, including
  3,600 m² class 8 clean room facilities
- **Market segments:** Diagnostics, Medical Devices and Pharma
- **Managing Directors:** Dr. Oliver Pfannschmidt, Stefan Holtkamp
Our home is the medical profession.
Your product ideas – perfectly realized

• Innovations workshop
• Concept study
• Freedom to operate study
• Requirements specifications
• Feasibility study
• Project plan

• High-precision injection molding
• Automated assembly
• Low-wage country assembly
• High speed automation
• Camera inspection
• Integrated supply-chain incl. Safety stock handling, VMI
• Lean manufacturing

• 3D data/2D drawing
• Device master record documentation (DMR)
• Prototypes PT
• Regulatory approval (CE, FDA et al)

• Performance specifications
• Design mock up
• Verification plan
• Cost calculation
• Design output review
• Design-for-x review

• CAD data 3D and drawings
• Project management
• Development reports
• Stage gate reviews with customer
• Functional samples
• Design output review
• Design history file documentation (DHF)
Our expertise

**Product development**
- Product concept study
- Design, form and function study
- Fully integrated product development
- Continuous stage gate reviews with customer
- Design for (cost, quality, manufacture) approach

**Product know how**
- Mechanics / kinematics
- Dosing of solids and liquids
- Packaging
- Plastics+electronics devices
- Plastics+optics devices

>> Our actions are creative and structured, blending innovation with systematic project management.
Industrialization

Process development
- Process automation
- IPC (in process control)
- Process robustness study
- Six Sigma approach
- CE Marketing

Production infrastructure
- Clean rooms
- Controlled area
- Automated warehousing
- In-house maintenance
- Lean (Pull, Flow) concept

Support processes
- Sourcing strategy
- Tool making
- Flexible shift pattern

>> Maximum precision and efficiency - from the concept to industrial production.
Production

High Precision Injection Molding
- 1K, 2K Multi cavity (up to 128)
- Thin wall
- Inserts (metal, glass)
- IML/IMD In-mold labelling/decoration
- Injection embossing (injection compression moulding)

Decorating
- Stamping
- Laser marking
- Printing

Assembling
- Automation of multi component assemblies
- Alternatively: low-wage assembly for small series
- Gass, metal, electronics PCB assembly expertise

Supply Chain
- Automated high bay warehouse with 4000 pallet places
- SAP R3 based customer planning schedule
- Just-in-time supply approach
- Safety stock for customer
- International manufacturing footprint, risk mitigation

>> We deliver your products just-in-time to any place in the world.
Quality Management

Design-to-quality
• Product design according to Lean/Design-to-quality approach
• SixSigma approach during industrial product life cycle

Quality systems
• Balda Quality Management Handbook
• Quality management processes according to ISO13485 as well as 21CFR820 guidelines
• Computer aided quality system (CAQ Guardus)
• Dedicated product and process validation process (DQ,IQ,OQ,PQ, FAT, SAT)
• Established CE and FDA registration capability

Quality control
• Dedicated quality planning group
• Independent quality control department
• On-shift quality measurement
• Electronic batch record documentation
• Gage Reliability and Repeatability studies (Gage R&R)
• Most advanced electronic and mechanic test equipment
Certificates

Balda Healthcare has a proven track record on successful authorities as well as customer audits. We are certified by ISO standards as well as US-FDA and European Medical Devices Directory (MDD).

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Reliability through partnership

Our spirit

• Long-term partnership
• Commitment
• Transparency
• Continuous improvement mentality
• Life cycle partnership with customer

Our competencies

• Product design
• Product development
• Large series production
• Operational Excellence, LeanSixsigma
• Global Supply Chain

>> We are an authentic, reliable and consistent partner.
Your product ideas – perfectly realized
Product examples:

- Drug Delivery Systems: Inhaler, tablet dispenser, safety syringe, powder dispenser
- Primary Packaging: tablet cartridges, glass-to-glass connectors, drug containers, tubes
Electronic Tablet Dispenser

Features

• Balda product responsibility from development to series manufacturing
• Hardware and software development
• Graphical user interface design
• Usability studies
• Product approval (CE) and implementation of FDA requirements

Project details

• Biocompatible materials: MABS, PARA, POM, PC, PBT, PMMA, TPU, PP, SEBS
• 16 plastic components incl. two-component, 10 purchase parts
• Fully-automated assembly process incl. electronic module
• Inline testing of mechanical and electrical functions
• Full-automated packaging concept for 80 countries
• Global supply chain service
Diagnostics customers

Product examples

• Hand-held devices: Blood glucose level testing devices, lancing devices, insertion devices

• Consumables: Pipette tips, cuvettes, tubes, PCR plates, point of care test cartridges
Racks with tips and cups

Features

• Racks with tips and cups for high-throughput immunochemistry (85 different tests)
• Burr-free tip
• High volumetric precision

Project details

• Tip material: electrical conductive PP
• Injection molded combi-rack, tip and cup (64 cavity tool)
• Fully automated 100% testing and assembly
• Industrialization incl. test system set-up
Product examples

• Valves
• Connecting pieces
• Prefilled syringes incl. safety features (needle trap)
• Dental care products
• Orthopedic products
Blood glucose tester

Features

• Ergonomically formed device design
• Scratch proof IMD display

Projekt details

• Material: ABS/PC, PC, PMMA, POM
• 6 plastic components, 6 purchased parts
• Semi automated assembly incl. ultrasonic welding
• Global supply chain service
Examples of Devices

Lancing Device
- 14 plastic, 6 metal parts
- PC/ABS, POM, PBT, PPS GF40
- manual assembly
- full design responsibility
- Country specific kit packaging
- annual volume: M5

Meter/Housing
- 18 plastic, 6 metal, 4 other components parts
- 3 sub assembly groups
- PC, PMMA, ABS, TPE
- fully automated assembly
- 2K, IMD high gloss
- annual volume: M2

Inhaler
- 15 plastic, 2 metal parts
- ABS, POM, PP, PBT, PEI
- manual assembly
- Product responsibility at Balda up to API filling
Examples of Disposables

**Twist & Break Tube**
- 2 plastic parts, PP
- 32 cavities, 6 sec. cycle time
- fully automated assembly
- 100% leakage tested
- Membrane of 0.06 mm as predetermined breaking point
- annual volume: M80

**Tips & Cups**
- 3 plastic parts
- PP (conductive) and PS
- 32 cavities, 6 sec. cycle time
- fully automated assembly including final packaging
- 100% camera inspection
- annual volume: 1,4Mrd.

**Connector Device**
- 1 plastic part,(2K)
- PC, TPE
- 16 + 16 cavities, 19 sec cycle time.
- fully automated assembly including final packaging
- 100% camera inspection
- annual volume: M20
THANK YOU FOR YOUR ATTENTION!

www.balda-group.com