



Implementation of serialisation & traceability at manufacturers – best practices

Angeline Riezebos

Sanquin Plasma Products

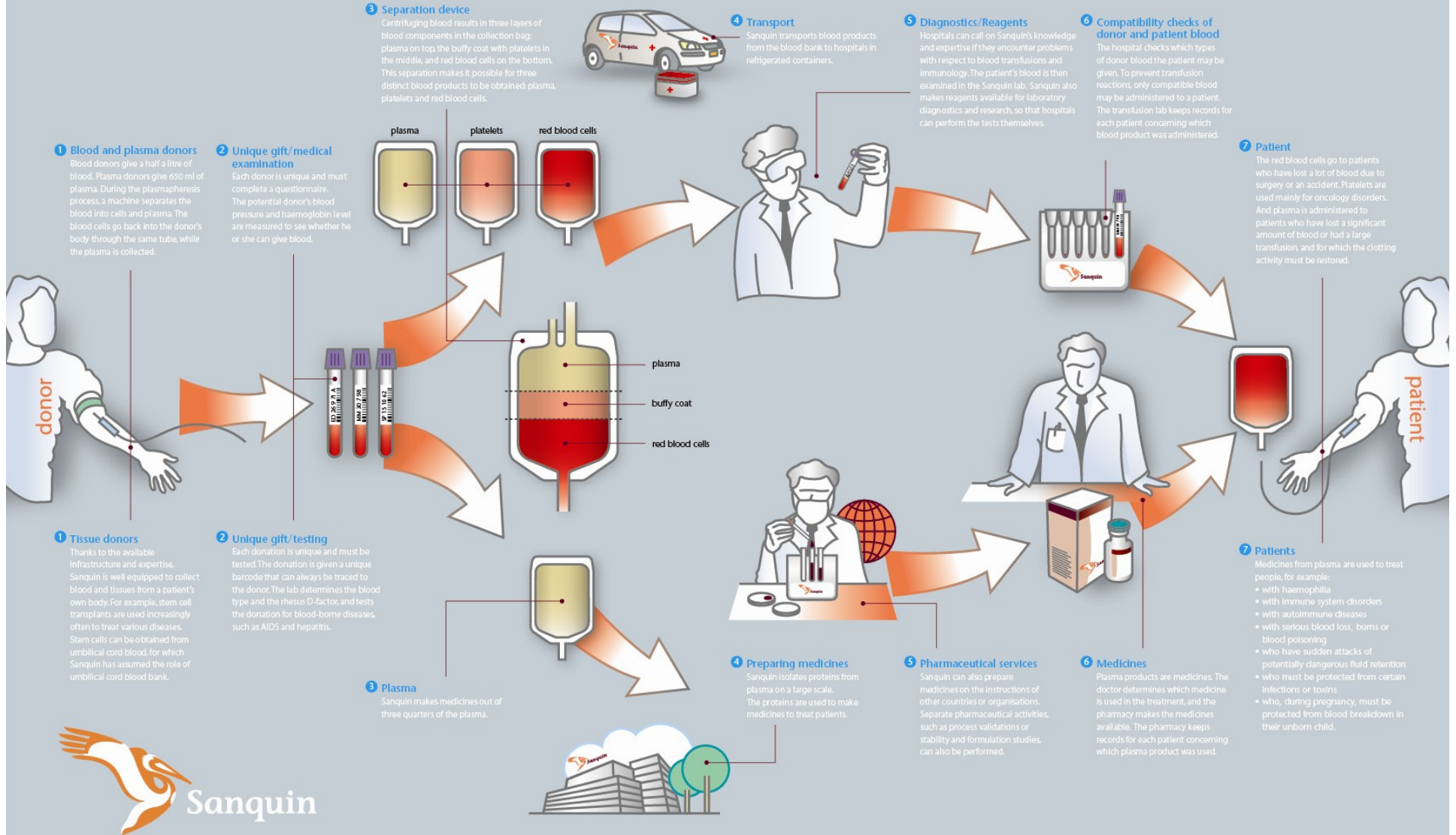
(a.riezebos@sanquin.nl)



About Sanquin

- Founded January 1998
- Sanquin is a merger between Central Laboratory of the Red Cross Blood Transfusion Service (CLB, founded WOII) and the Dutch Red Cross blood banks
- Sanquin is responsible for supplying blood in The Netherlands on a not-for-profit basis - donors give blood on a voluntary basis
- 5 divisions: Blood Bank, Plasma Products, Reagents, Diagnostic Services & Research

FROM DONOR TO PATIENT, FROM BLOOD TO MEDICINE



Production of human pharmaceuticals

- Sanquin registrations
 - National Marketing Authorisation procedure: 5 products
 - EU- Mutual Recognition Procedure: 5 products
 - European Medicines Agency: 1 product
- Production for Contract Manufacturing
- Delivery of products to:
 - EU
 - Switzerland
 - Turkey
 - Australia
 - US
 - Canada
 - Brazil
 - Indonesia

Plasma Products & Traceability



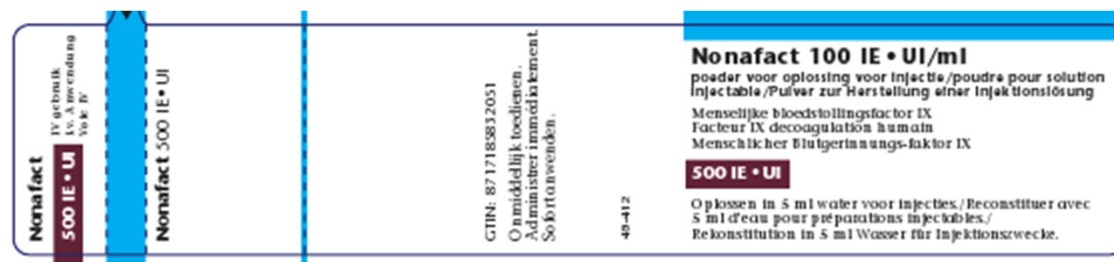
- Traceability of plasma products
 - 1993: Dutch Law - batch administration Dutch hospitals for some products
 - 1996: HIBC barcode & peel off labels & leaflet: Lot
 - 1997: Change of law - Plasma products became human pharmaceuticals
 - Registration national, MRP, EMA
- Human pharmaceuticals:
 - European Federation of Pharmaceutical Industries and Associations
 - 2006: all secondary packing materials: GS1 Datamatrix
 - Dutch Symposium 2010: bedside scanning
 - EU-directive Falsified Medicine published July 2011
 - Meeting with Dutch Hospital Pharmacists Association (NVZA): bedside scanning

What to do to implement GS1 Datamatrix

- Become a member of GS1
 - 2002: company code: 871718583
 - 2009: EAN-13 to Dutch cartons
- Identify Application Identifiers (AI): (01)GTIN (17) EXP (10) Lot
 - new AI needed Active Potency: (7004)
- Create a S.O.P. with products and GTIN
- Investigate which packaging materials had to change
- Can packaging machines print datamatrix?
- Distribution department
- Validations
- Training

Sanquin packaging materials

- All labels were adjusted
- All cartons were adjusted
- Artwork was sent to regulatory authorities
 - EMA: great help to get all text on the labels (8 ml vial – 3 languages!)
 - MRP: questions about GTIN
 - National Authority: no questions



Packaging department



Distribution department

- SAP Sales module adjusted
 - Products with HIBC or Datamatrix (GS1)
 - New scanners (camara-based): linear and 2-dimensional
 - Computer validation (GAMP)

Status

- National: week 45 2013 1st product was delivered
- MRP: 3 products: GTIN included on 2
- EMA: 1 product : GTIN included & delivered to NL,FI, B



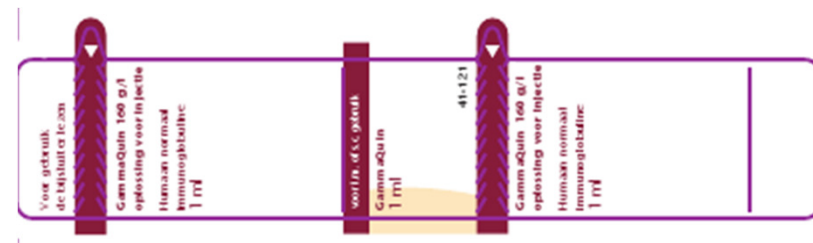


Special issues



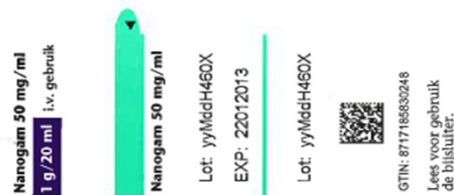
Bedside scanning: vial (1)

- One pack with 2 different vials: water for injections and freeze dried product
 - 3 different GTINs: carton, 2 vials
- Size of datamatrix on labels – 2ml, 8ml, 15ml, 50ml, 100 ml, 250 ml, 500 ml vials
- New label 2 ml vial



Bedside scanning vial (2)

- Too much regulatory text on vials
- Space needed for the GTIN number & 2D-code
- Some countries do not allow a turn-around label
- Some countries require 2 peel off labels

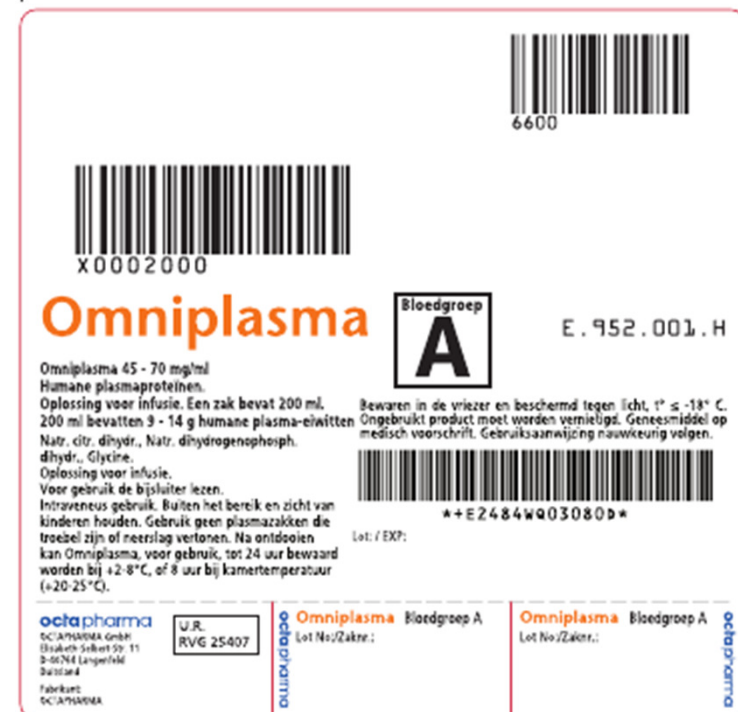


Local Database needed?

- Database Belgium?
 - Sanquin products: 2 products with datamatrix
 - CAF-DCF: 2 products with datamatrix
- Database Finland?
- How can a distributor add to a local data base.
(Not every one speaks local language)

A special human pharmaceutical

- Pooled plasma product
- Product is distributed by Blood Banks: ISBT-128
 - NL – 5 barcodes
 - Unit number
 - Blood group code
 - Product code
 - EXP date
 - Pharmaceutical code
- traceability on “unit number” = serial number
- Is there a need for datamatrix according to EU directive FM
 - IT problem Blood Banks & hospitals?



6600

X0002000

Omniplasma **Bloedgroep A** E.952.001.H

Omniplasma 45 - 70 mg/ml
Humane plasmaproteïnen.
Oplossing voor infusie. Een zak bevat 200 ml.
200 ml bevatten 9 - 14 g humane plasma-eiwitten

Natr. citr. dihydr., Natr. dihydrogenophosph. dihydr., Glycine.
Oplossing voor infusie.
Voor gebruik de bijsluiter lezen.
Intraveneus gebruik. Buiten het bereik en zicht van kinderen houden. Gebruik geen plasmazakken die troebel zijn of neerslag vertonen. Na ontdooien kan Omniplasma, voor gebruik, tot 24 uur bewaard worden bij +2-8°C, of 8 uur bij kamertemperatuur (+20-25°C).

Bewaren in de vriezer en beschermd tegen licht, 1° ≤ -18° C.
Ongebruikt product moet worden vernietigd. Geneesmiddel op medisch voorschrift. Gebruiksaanwijzing nauwkeurig volgen.

Lot: / EXP: *+E2484WQ03080D*

octapharma
DCLAPHARMA GmbH
Bismarck-Straße 59-11
D-06294 Langerfeld
Balsdorf
Fabrikant
DCLAPHARMA

U.R.
RVG 25407

octapharma
Omniplasma Bloedgroep A
Lot No./Zaknr.:

octapharma
Omniplasma Bloedgroep A
Lot No./Zaknr.:

More countries on one pack

- EMA- registration: Cinryze (Sanquin = manufacturer & distributor)
 - Two countries one pack: UK & Germany
 - Two countries one pack: Finland & The Netherlands
 - Vnr code and GTIN code: do we need to add Vnr as (AI)
 - Only one datamatrix on carton
 - Will Dutch customers be able to handle the AI: Vnr-code



GTIN: 5060147020687

BATCH/Erä/Sats:

yyMddH370X

EXP/Käyt. vlim./
Utg.dat.:

01/2015



29-430

Medical devices

- Medical devices in an administration kit delivered together with a pharmaceutical product
 - composed according to article 12 of the directive medical devices 93/42/EEC.
 - No CE logo
- Medical devices in a pharmaceutical pack
- Serialisation needed in the future???
- SAP: Display batch - Where used list



Complaints of customers

- Dutch hospital: cannot read datamatrix

Sales manager upset

Status Serialisation

- All machines can print a serial number
- Do we need to print serial numbers (20 characters) on the product carton ?
- SAP and production machines are not linked – project starts end 2014
 - How do we cope with GTIN on vials
 - 3 GTIN per product!
- Datamatrix is printed on the site of cartons – aggregation problem?
 - Not a lot of space on top of the small cartons (34 x 34 mm)





GS1: Your help is needed



Special thanks..

- Sarine Pielaat, AIDC expert GS1 the Netherlands
- Helen Stuart, Process Engineer Sanquin Plasma Products